

## Instructions for use ACCUJECT



## 1. Scope of application

These instructions for use apply to the following medical devices:



Reference number	Product name	510(k) number
LP604590	ACCUJECT 2.1-IP Injector Set	K252540


## 2. Scope

**Intended use:** The ACCUJECT Injector Set is a device intended to fold and insert BVI IOLs approved for use with this injector in the human eye.

**Indication:** Visual problems that require implantation of IOL.

**Contraindications:** There are no specific contraindications for the injectors, apart from general contraindications related to ophthalmic surgery.



  **User Group:** The medical device must only be handled by healthcare professionals and applied to the patient by the surgeon. Use by unqualified personnel could result in patient injury.


 **Patient Group:** A patient-related, careful preoperative assessment, with well-founded clinical judgment and risk-benefit assessment, is the responsibility of the surgeon.


**Clinical benefit:** IOL injector allows IOL implantation through small incisions.


## 3. Notes on safety


The suitability of the intraocular lens (IOL) in combination with the medical device (IOL injector) must be tested and approved in advance by the intraocular lens manufacturer. Please refer to the specific instructions for use provided with the IOL.



  **Warning**  
Using a damaged or non-sterile medical device can lead to infection / endophthalmitis in the patient. Do not use the medical device if there are signs of damage to the medical device itself or to the sterile packaging.

 **Warning**  
The medical device must not be used after the expiry date. Use after the expiration date may result in infection / endophthalmitis of the patient.

 **Warning**  
Touching the endothelium with the silicone cushion or IOL can damage the corneal endothelium.

 **Warning**  
Appropriate surgical technique is the responsibility of the individual surgeon. The surgeon has to assess the suitability of the respective procedure on the basis of his / her training and experience.

 **Warning**  
The medical device is intended for single use only. Reuse or inappropriate reprocessing may lead to serious adverse effects on the health and safety of the patient.

 - Reuse may result in infection / endophthalmitis, TASS or allergic reaction due to cleaning residues.  
 - The performance of the medical device may be compromised. Heat or the cleaning process will destroy performance properties (e.g. mechanical properties and gliding properties) of the medical device.

 **Caution**  
In order to avoid capsule rupture, the IOL must be injected slowly and carefully into the eye.

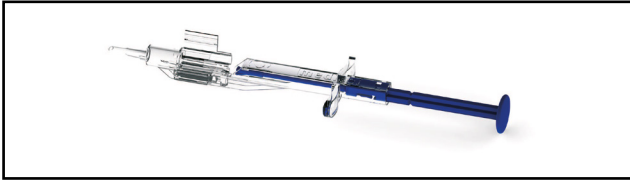


#### 4. Reporting to manufacturer and authorities

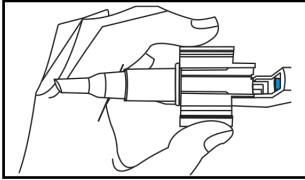
Serious incidents occurring in connection with the device must be reported to the manufacturer and the competent authority in which the user and/or patient is established.

#### 5. Application instructions for the single-use IOL injector

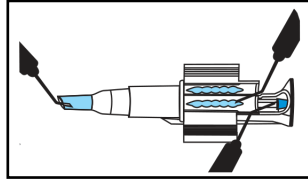
1. Open the blister in a sterile environment and remove the sterile injector.
2. Hold the injector so that the rear wing of the loading chamber can be guided with the index finger of your left hand (2).
3. Fill the cartridge tip (3a) and loading chamber (3b) sufficiently with ophthalmic viscosurgical devices (OVD).  
  
It is recommended to flush the cartridge tip and the loading chamber with Balanced Salt Solution (BSS) before the application of OVD.  
  
Allow the OVD to react (30s). OVD can lose their lubricating properties if they are in contact with air for too long. Therefore, the IOL should be injected without delay after loading.  
  
Hydrophobic IOL types: The application of OVD is required. The exclusive use of BSS is not permitted. In addition, apply a drop of OVD to the silicone cushion (3).
4. Open the loading chamber so that the IOL can be easily loaded.  
Position the IOL in the middle of the loading chamber (4) with a concave orientation.
5. Use the sterile forceps to apply slight pressure to the IOL optics (5), this ensures that the IOL folds in a concave direction. Make sure that all haptics are inside the loading chamber under the grooves before further closing it. For IOLs with C-loop haptics, align the haptics with sterile forceps in the direction of the optics.
6. At the same time, close the wings of the loading chamber until the „Click-Lock“ mechanism engages (6).
7. Damaged or broken haptic can occur when the IOL injector is used improperly. To mitigate the risk of IOL damage: Check that haptics are not trapped in the closing elements of the loading chamber, which could lead to haptics damage after the IOL is loaded and the loading chamber closed.
8. Push the injector plunger forward.  
  
If the silicone cushion is inclined and cannot be inserted into the closed loading chamber, the silicone cushion can be aligned with the forceps.
9. Push the injector plunger forward until the silicone cushion reaches the front end of the injector housing (7).  
  
Pull back the injector plunger a few millimetres and then push it forward again. This step ensures that the IOL is always gripped correctly.  
  
The IOL is now loaded and ready for injection.
10. Slowly inject the IOL into the eye by applying pressure to the injector plunger.
11. The correct exit of the IOL can be supported by turning the injector slightly. Only push the injector plunger forward until the IOL has emerged completely.
12. If necessary, assist the IOL with the help of a suitable positioning hook during the exit and bring the IOL into its final position.
13. Thoroughly remove the viscoelastic material from the eye and IOL using standard irrigation and aspiration techniques.



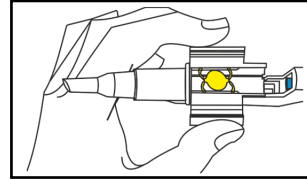
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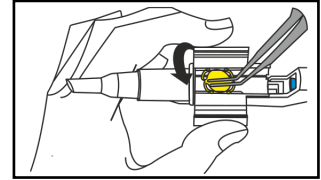
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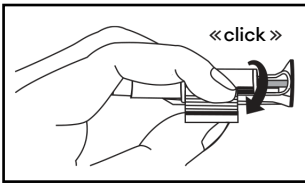
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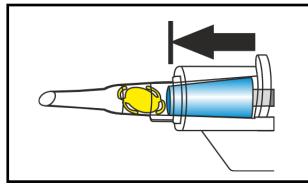
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## 6. Disposal

### Warning

The medical device may be contaminated with potentially infectious substances of human origin after use.

Dispose of the medical device and packaging after use according to the applicable guidelines of biological hazardous waste.

## 7. Symbols

	Sterilized using ethylene oxide		Keep dry
	Number of medical device in packaging unit		Do not use if package is damaged and consult instructions for use
	Single sterile barrier system		Keep away from sunlight
	Single sterile barrier system with protecting packaging outside		Do not re-sterilize
	Date of manufacture YYYY-MM-DD and country of manufacture		CE symbol with number of the notified body
	Do not re-use		Authorized representative in the European Community / European Union
	Reference number		Open here
	Lot number		Unique device identifier
	Expiry date		Medical device
	Manufacturer		Consult electronic instructions for use
	To be used by qualified personnel only		Caution
	Recycling		