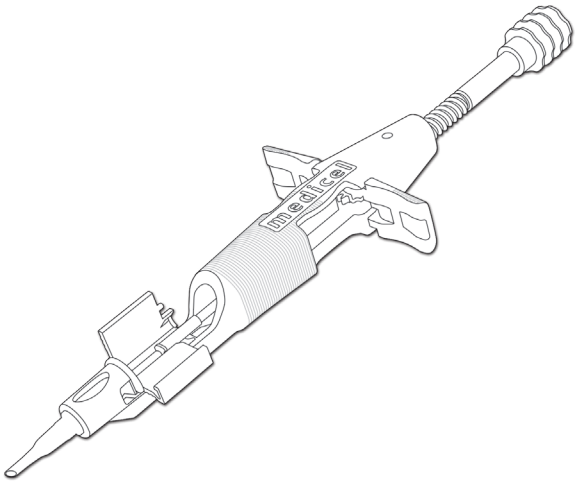
ACCUJECT™ REFRA



Instructions for use Accuject Refra

GAARSTA_rev02_22.09.2023

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CE 0482

ACCUJECT™ REFRA

1. Scope of application

These instructions for use apply to the following medical devices:

Reference number	Product name
AR2900	Accuject REFRA 2.9 Injector

2. Scope

Intended use: The Accujet REFRA Injector is a device intended to fold and insert STAAR Surgical Collamer Phakic One Piece Intraocular Lenses, Model EVO/EVO+ VISIAN® Implantable Collamer® Lens, for surgical placement 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.

⚠ ℞ ONLY 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.

⚠ **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.

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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 (1).

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 sufficiently with ophthalmic viscosurgical devices (OVD) and the loading chamber with Balanced Salt Solution (BSS) (3).

   It is recommended to flush the cartridge tip and the loading chamber with 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.

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).

5. Use the sterile forceps to apply slight pressure to the IOL optics (6), this ensures that the IOL folds in a concave direction.

6. At the same time, close the wings of the loading chamber until the „Click-Lock“ mechanism engages (7).

7. Push the injector plunger forward with the finger flanges folded in.

   If the silicone cushion is inclined and cannot be inserted into the closed loading chamber, the silicone cushion can be aligned with the forceps.

8. Advance the IOL into the conical tip of the cartridge as far as it will go or until half of the silicone cushion is visible in the viewing window (8).

   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.

9. Syringe injector: unfold the finger flanges.
   Screw injector: leave the finger flange folded in.

   The finger flanges must be fully retracted for use in screw mode.

10. Rotate the injector so that the wing of the loading chamber is pointing down and the IOL exits in the correct orientation (9).

11. Slowly inject the IOL into the eye by either applying even pressure to the injector plunger (syringe injector), or slowly turning the injector plunger knob clockwise (screw injector) (10).

12. 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.

13. If necessary, assist the IOL with the help of a suitable positioning hook during the exit and bring the IOL into its final position.

14. Thoroughly remove the viscoelastic material from the eye and IOL using standard irrigation and aspiration techniques.

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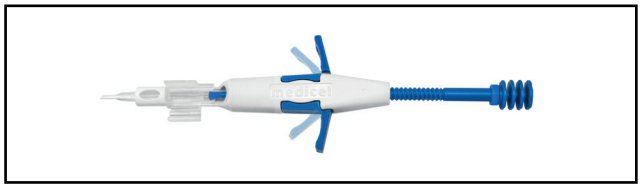
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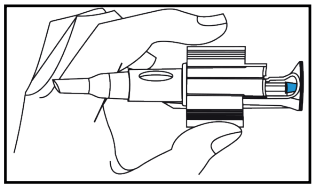
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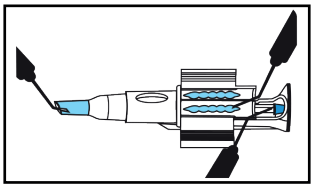
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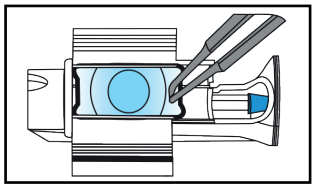
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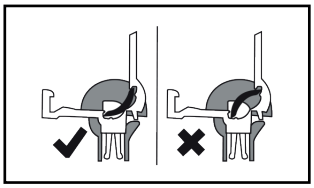
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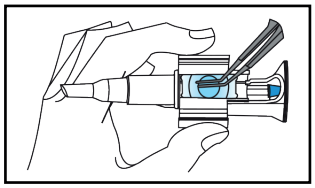
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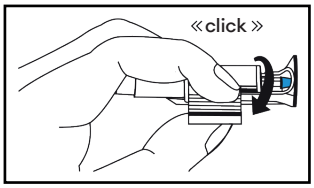

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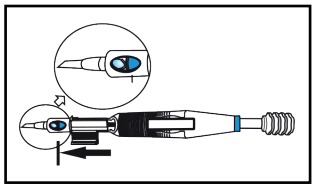
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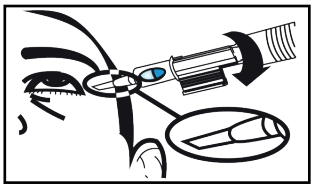
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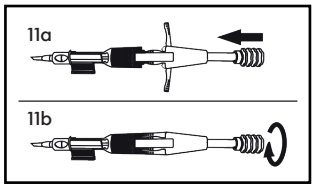

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6. Disposal
Warning
The medical device may be contaminated with potentially infectious substances of human origin after use.
Dispose of the medical device and packaging after use according to the applicable guidelines of biological hazardous waste.

7. Symbols

STERILE EO	Sterilized using ethylene oxide		Keep dry
Σ	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
CH	Date of manufacture YYYY-MM-DD and country of manufacture	CE 0482	CE symbol with number of the notified body
	Do not re-use	EC REP	Authorized representative in the European Community / European Union
REF	Reference number		Open here
LOT	Lot number	UDI	Unique device identifier
	Expiry date	MD	Medical device
	Manufacturer	www.medicel.com/ifu	Consult electronic instructions for use
Rx ONLY	To be used by qualified personnel only		Caution
	Recycling		

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