



## SAFELoader® Instructions for use

### 2-Component Autoloading System

**Important:** Only valid in connection with the instruction for use of Acrylic IOLs manufactured by HumanOptics Holding AG.

**These instructions for use apply for the SAFELoader® 2-Component Autoloading System with the below-mentioned injectors manufactured by Medical AG. The injectors are manufactured exclusively for HumanOptics Holding AG and feature a yellow plunger.**

INJECTOR SYSTEM/CARTRIDGE	C-Loop IOLs (ending -aI/-aV) Fig. 2a	XL Optic IOLs (ending -aX/-aXV) Fig. 2b
Accuject™ 1.8-1P LP 604540 Medical AG, Switzerland	Rev. C	–
Accuject™ 2.0-1P LP 604510	Rev. C	Rev. B
Accuject™ 2.2-1P LP 604530	Rev. C	–

#### Description of the SAFELoader®

The SAFELoader® 2-Component Autoloading System is composed of an Accuject™ injector with a yellow plunger and an integrated cartridge (manufacturer: Medical AG) and an autoloading container with a produced acrylic intraocular lens (IOL) (Fig. 1).

#### Using the SAFELoader®

- Before implantation, check the lens package for the correct lens model and dioptric power.
- Check also the expiration dates of the lens and the injector. The lens and the injector should not be used after the indicated expiration dates.
- Before use, check the integrity of the sterile barrier system of the lens and the injector. The IOL and the injector are sterile only if the sterile pouch is undamaged.
- The blister packaging of the autoloading container and the injector should be opened just before use by pulling the Tyvek foil off. The autoloading container and the injector must be removed from their packaging under sterile conditions.

**Attention:** The outer blister packaging is not sterile.

- **Do not use** the product if the sterile barrier system is damaged or if liquid is leaking from the container.

- Before use, the IOL should be warmed to temperatures between 18 °C (operating room) and 36 °C (internal temperature of the eye) to avoid damage to the IOL during implantation.

**Attention:** The IOL must not dehydrate! Hydrophilic acrylic IOLs should be moistened in isotonic saline solution only.

#### Implantation

- The capsulorhexis diameter should be approximately 0.5 mm smaller than the IOL optical diameter.
- Before implantation fill the anterior chamber and capsular bag adequately with viscoelastic material in order to ensure a smooth and safe IOL implantation.
- During implantation, ensure the correct anterior / posterior orientation of the IOL: C-loop haptics are pointing from the optics in a counterclockwise direction (anterior view, Fig. 2a). The IOL may

be rotated clockwise to the appropriate axis, as is the usual case with posterior chamber lenses. IOLs with cut-out haptic design are correctly oriented when one marking appears on the top right and the other marking on the bottom left (Fig. 2b).

- Follow the instructions for use of the Accuject™ injector and check its suitability for use with reference to the IOL power. If in doubt consult the manufacturer.
- The sterile OR team member removes the SAFELoader® from the proffered packaging container (Fig. 3).
- Grasp the sealing foil on the autoloading container where the tab sticks out and pull it off (Fig. 4).
- Open the Accuject™ injector's cartridge completely (Fig. 5).
- Hold the Accuject™ injector's handle in one hand and insert the cartridge wings into the two outer slots of the autoloading container (Fig. 6).
- Press the Accuject™ injector down and hold it in this position while rotating the injector clockwise to the stop (Fig. 7).
- Pull the Accuject™ injector out of the autoloading container. One wing of the cartridge exits the autoloading container from the middle slot (Fig. 8a and 8b).
- Check that the IOL has been correctly loaded. The IOL should be in the center of the loading chamber between the silicone plunger and the beginning of the cartridge tunnel (Fig. 9a and 9b). If necessary, align the haptics with the sterile tweezers close to the optic and ensure that they are inside the loading chamber. The position of the cartridge wings in relation to each other must not be changed.
- Close the Accuject™ injector's cartridge while at the same time applying slight pressure to the lens optic with the forceps. This ensures that the lens folds in the correct direction. The lens is securely loaded and ready for injection as soon as the "click-lock" mechanism has engaged (Fig. 10a and 10b). The lens should be injected immediately after insertion into the cartridge tunnel.\*
- Press the injector plunger with the silicon plunger forward and push the IOL into the conical tip of the cartridge.  
**Important:** Pull the plunger back a few millimeters and then push forward again. This step ensures that the IOL is always grasped correctly.\*

- Insert the tip of the cartridge through the incision and push it over the iris to the near edge of the pupil.\*
- Press the plunger with the silicon plunger forward slowly in order to push the lens forward.\*
- Inject the lens slowly into the capsule bag and withdraw the injector from the eye.\*

#### Notes

The autoloading container is only compatible with the Accuject™ injector (1.8, 2.0, 2.2) with a yellow plunger made by Medical AG.

There is a risk that an excessive amount of viscoelastic material in the region of the loading chamber will cause the IOL to fold in the wrong direction when the cartridge is closed. The IOL might then exit the nozzle wrong sided.

If difficulties should develop during the implantation, the implantation must be stopped and a new product must be used.

Do not insert the wings of the injector into the middle opening of the SAFELoader® container.

Do not insert the injector from an angle.

Do not push accidentally the push rod when inserting the injector.

Do not pinch the haptics with the cartridge wings.

#### Reprocessing

Reprocessing of the implant is strictly prohibited, since material changes, for example, may cause serious complications and can be fatal.

#### Disclaimer

The manufacturer is not liable for the implantation method or the operative technique used by the physician performing the procedure or for the selection of the IOL in relation to the patient or his condition.



Fig. 1: System components of the SAFELoader®: autoloading container (bottom), Accuject™ (top)

\* According to instructions for use of the injector AccuJect™.  
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Please visit [www.humanoptics.com](http://www.humanoptics.com) for more information and scan the QR code to view an application video:

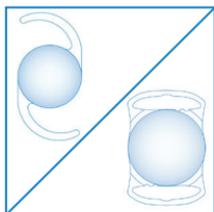


Fig. 2a/2b



Fig. 3



Fig. 4

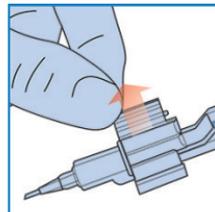


Fig. 5

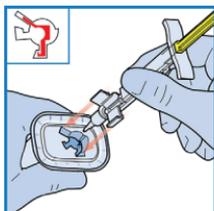


Fig. 6



Fig. 7

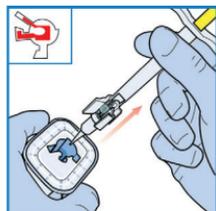


Fig. 8a

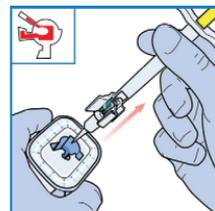


Fig. 8b

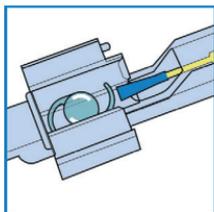


Fig. 9a

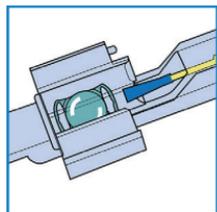


Fig. 9b

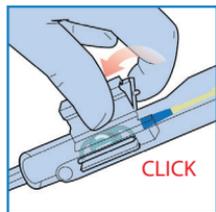


Fig. 10a

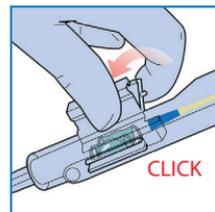


Fig. 10b

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