

ENGLISH

Medicel VISOJECT™

Multiple-use titanium injectors
(injecting and rotating version)
for injection of
ONE-PIECE FOLDABLE ACRYLIC LENSES

DEUTSCH

Medicel VISOJECT™

Mehrweg-Injektoren aus Titan
(Spritzen-und Drehversion)
zur Injektion von
EIN-TEILIGEN FALTBAREN ACRYL-LINSEN

FRANÇAIS

Medicel VISOJECT™

Injecteurs en titane à usage multiple
(version pour injection et rotation)
pour l'injection de
LENTILLES EN ACRYLIQUE MONOBLOC
PLIABLES

ITALIANO

Medicel VISOJECT™

Iniettori in titanio multiuso
(versione per iniezione e per rotazione)
per l'iniezione di
LENTI ACRILICHE PLEGHEVOLI MONOPEZZO

ESPAÑOL

Medicel VISOJECT™

Inyectores reutilizables de titanio
(versión de inyección y giro)
para la inyección de
LENTES ACRÍLICAS PLEGABLES
DE UNA PIEZA

TÜRKÇE

Medicel VISOJECT™

cök kullanılmaktı titanium enjekktörler
(enjeksiyon ve dönüştürücü versiyon)
Tek parça
KATLANABİLİR AKRİLİK LENS
enjeksiyonu için

DESCRIPTION

The cartridge may only be used once and not resterilized/treated. Reuse or resterilization may reduce the product's performance, which can result in serious impairments to the patient's health and safety. Store cartridge set at room temperature.

APPLICATION
Folding and injecting of one-piece acrylic lenses into the capsular bag of sulcus after extra-capsular cataract extraction. Three-piece foldable intraocular lenses are not suited for implantation using the VISOJECT™ injection system.

IMPORTANT: When using hydrophobic lenses, let the viscoelastic solutions work for about 30 seconds to achieve sufficient hydration of the lubricating film. After 30 seconds the lens should be injected immediately. Viscoelastic materials may lose their lubricating properties when exposed to air for a longer period of time.

ATTENTION: US federal regulations restrict the sale of this product to medical practitioners and those acting on their behalf.*

The VISOJECT™ injection system consists of three parts:
1. The reusable VISOJECT™ titanium Injector (Fig. 1a, 1b)
2. The silicone tip (Fig. 2)
3. The sterile, VISOJECT™-BIO or VISOJECT™ single-use cartridge (Fig. 3)

INSTRUCTIONS FOR USE
1. Clean, disinfect and sterilize the VISOJECT™ injector (Fig. 1a, 1b) according to the instructions for use for the multiple-use injector "Treatment pursuant to EN ISO 17664" and place it in a sterile environment.
2. Open the blister package in the sterile area and remove the injector and cartridge.
3. Place the foldable lens on the central hinge of the opened cartridge symmetrically as shown in Fig. 6. Align one-piece

3. Take the mounting with silicone tip and place the silicone tip on the direction of the cartridge regardless of the one-piece design. Asymmetric insertion of the lens can lead to rotation of the lens in the injector.
4. Completely fill the cartridge tunnel of the VISOJECT™ cartridge with viscoelastic solution and fill the loading chamber with sufficient viscoelastic solution (Fig. 5). In addition, apply a drop of viscoelastic solution to the silicone tip. The exclusive use of balanced salt solution (BSS) is not permitted.

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lenses in the direction of the cartridge regardless of the one-piece design. Asymmetric insertion of the lens can lead to rotation of the lens in the injector.
5. Ensure that the lens is correctly aligned and be careful that when closing, neither the edge of the lens nor the haptics are wedged in. For lenses with C-loop haptics, align these in the direction of the lens using sterile tweezers (Fig. 8).
6. Press the cartridge sides together until the "click-lock" mechanism engages (Fig. 9).
7. Insert the cartridge into the front end of the injector. Push the cartridge into the very front position (Fig. 10).
8. Slowly push the plunger forward (the lens is pressed forward almost without contact as a result of the pressure created by VISOJECT™). Depending on the lens model, support the correct ejection of the lens by slightly

9. Insert the cartridge into the front end of the injector. Push the cartridge into the very front position (Fig. 10).
10. Carefully push the plunger forwards and ensure that the silicone tip correctly enters the loading chamber. If the silicone

tip cannot be introduced into the loading chamber, retract the plunger to the starting position and align the silicone tip straight with the direction of the lens in the injector.
11. Press the lens into the front part of the cartridge point outside of the eye. This prevents pressure generated by the VISOJECT™ system and an increased quantity of viscoelastic solution from being transferred to the eye.

12. Insert the cartridge tip through the incision and slide it over the pupil. Slowly push the plunger forward (the lens is pressed forward almost without contact as a result of the pressure created by VISOJECT™). Depending on the lens model, support the correct ejection of the lens by slightly

turning the injector. Slowly inject the lens into the eye and simultaneously withdraw the instrument from the eye. To avoid swelling of the silicone tip during ejection from the cartridge only push the plunger until the lens has emerged completely, even if the plunger is not yet at the limit.
14. Carefully position the lens, rotating it if necessary with the aid of a suitable positioning hook.

15. Remove the viscoelastic material thoroughly from the eye and the lens with the standard irrigation and aspiration techniques.
16. The VISOJECT™ injector can be reused after treatment (cleaning, disinfection and sterilization).

REUSABILITY
The instruments can be reused as long as they are handled carefully and are undamaged and uncontaminated. The user takes responsibility for the use of damaged or contaminated instruments. Any liability is excluded if the instruments are not used as intended.

PLEASE NOTE:
The injector's cartridge may not be treated or resterilized. The cartridge may only be used once. Information concerning the use of the cartridge is contained in the instructions for use of the VISOJECT™ and MULTIJECT™ injector set.

OPERATIONAL PROCEDURE
The appropriate surgical techniques are the responsibility of the respective surgeon. He or she must assess the appropriateness of the relevant procedure based on his or her education and experience.

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GUARANTEE AND LIMITATION OF LIABILITY
The manufacturer guarantees that this product was produced with appropriate care and shall assume no responsibility for incidental or consequential damages, losses or costs that should result directly or indirectly from the use of this product. Liability is solely limited to claim-related repairs that must be performed on the product which are clearly not attributed to incorrect handling or the use of lenses not validated for this injector model.

LOT Batch code

Use by Use by

Keep dry Keep dry

Keep away from sunlight Keep away from sunlight

Manufacturer Manufacturer

Do not use if package is damaged Do not use if package is damaged

STERILE Sterilized using Ethylene Oxide (EO)

B ONLY *

VISOJECT™-BIO
VISOJECT™



medicel
SWISS TECHNOLOGY FOR SURGERY

Instructions for use
Gebrauchsanweisung
Instructions d'utilisation
Istruzioni per l'uso
Instrucciones de uso
Kullanım Talimatları

使用说明书

Bruksanvisning
Инструкция по применению
Instrucciones de uso

Návod k použití
Brugsanvisning

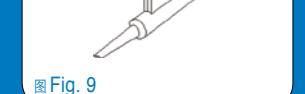
사용 설명서

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