DRAFT_PROJECT NOTICE

Ref : Cartinject_eifu-rev O_DRAFT_en

CARTINJECT

CE 1639

Manufacturer

MDJ SAS, ZI Racine Palladuc, 63650 LA MONNERIE LE MONTEL, FRANCE

en WARNING AND INDICATIONS FOR USE

IT IS IMPORTANT TO READ THIS DOCUMENT CAREFULLY
Do not hesitate to ask the distributor's sales department for advice if you need further information.

DESTINATION

The intraocular injection system CARTINJECT is designed to inject a soft, foldable intraocular lens (IOL) into the patient's eye during cataract surgery.

DESCRIPTION

CARTINJECT is an intraocular injection system consisting of an injector and a cartridge. Some versions of CARTINJECT include a reamer.

Reference	Basic UDI
CARTINJECT	376034321IOLINJECT

CARTINJECT is supplied sterile and is for single use only.

MATERIALS CONSTITUTING THE DEVICE

Injector:

- Polycarbonate for the injector
- Polyetherimide for the plunger
- Stainless steel for the spring
- Implantable silicone for the silicon tip

Cartridge :

- Polypropylene

Reamer :

- Polycarbonate for the Reamer
- Implantable silicone for the silicon tip

COMPATIBILITY BETWEEN PROVISIONS

SKU	Product designation Finished (trade name)	Size Incision (mm)	Lens Intraocular
K1.5M42	Cartinject 1.5	1.6 mm	IOL MICS (micro surgery lens) only
K1.5M42P	Cartinject 1.6 with reamer	1.6 mm	IOL MICS (micro surgery lens) only
K1.8M42	Cartinject 1.8	1.8 mm	IOL MICS (micro surgery lens) only
K1.8M42P	Cartinject 1.8 with reamer	1.8 mm	IOL MICS (micro surgery lens) only
K1.8M14	Cartinject 1.8	1.8 mm	IOL MICS (micro surgery lens) only
K1.8M14P	Cartinject 1.8 with reamer	1.8 mm	IOL MICS (micro surgery lens) only
K1.9M14P_CZM	Cartinject A6 with reamer	<2.0 mm	IOL MICS (micro surgery lens) only
K2.0M14	Cartinject 2.0	2.0 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.0M14P	Cartinject 2.0 with reamer	2.0 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.0M52P_BL	Cartinject MDJ 2.0-2.2 with reamer	<2.2 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.2M14_MBI	Cartinject MBI 2.2	2.2 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.2M14_ADM	Cartinject ADM 2.2	2.2 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.2M14P_ADM	Cartinject ADM 2.2 with reamer	2.2 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.2M14_AN	Cartinject Alpha Net 2.2	2.2 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.2M14P_AN	Cartinject Alpha Net 2.2 with reamer	2.2 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.2M52	Cartinject 2.2	2.2 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.2M52P	Cartinject 2.2 with reamer	2.2 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.2M14	Cartinject 2.2	2.2 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.2M14P	Cartinject 2.2 with reamer	2.2 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.3M14	Cartinject 2.2-2.4	<2.4 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.3M14P	Cartinject 2.2-2.4 with reamer	<2.4 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.3M14_ADM	Cartinject ADM 2.2-2.4	<2.4 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.3M14P_ADM	Cartinject ADM 2.2-2.4 with reamer	<2.4 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.4M52	Cartinject 2.4	<2.4 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.4M52P	Cartinject 2.4 with reamer	<2.4 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.4M14	Cartinject 2.4	<2.4 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.4M14P	Cartinject 2.4 with reamer	<2.4 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.5M52	Cartinject 2.4 R+	2.4 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs

K2.6M62_ADM	Cartinject ADM 2.4 HB	<2.6 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.6M62P_ADM	Cartinject ADM 2.4 HB with reamer	<2.6 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.6M62	Cartinject 2.6	<2.6 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K2.6M62P	Cartinject 2.6 with reamer	<2.6 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
K3.0M14	Cartinject 3.0	3.0 mm	Hydrophobic or hydrophilic acrylic IOLs (all models)
K3.0M14P	Cartinject 3.0 with reamer	3.0 mm	Hydrophobic or hydrophilic acrylic IOLs (all models)
K3.0MT	Cartinject Meplat	3.0 mm	Hydrophobic or hydrophilic acrylic LIOs (3 pieces)
K3.0MTP	Cartinject Meplat with reamer	3.0 mm	Hydrophobic or hydrophilic acrylic LIOs (3 pieces)
K3.0DZ	Cartinject Dezax	3.0 mm	Hydrophobic or hydrophilic acrylic LIOs (3 pieces)
K3.0DZP	Cartinject Dezax with reamer	3.0 mm	Hydrophobic or hydrophilic acrylic LIOs (3 pieces)

CLINICAL PERFORMANCE
Injection of a soft, foldable intraocular lens into the patient's eye during cataract surgery.

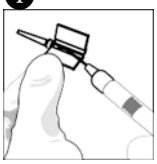
INDICATIONS FOR USE
Cataract surgery

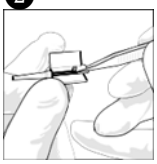
TARGET POPULATION
Adult patients for whom cataract surgery is planned

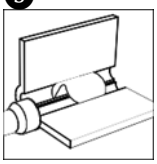
CONTRAINDICATIONS
A smaller incision size than the cartridge size
An infection, or latent infection
Known allergy to any component of the material
Use with a PMMA intraocular lens

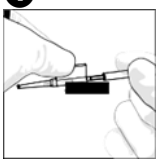
PRECAUTIONS/WARNING
- CARTINJECT Intraocular Injection Systems should be used in an aseptic and hygienic operating room by an ophthalmic surgeon who regularly performs cataract surgery with soft, foldable lenses.
- Prior to clinical use, the surgeon and operating room staff should be trained in the use of the device and how to use it.
- If important information on the label (com number, size, batch number) is not legible, do not use the device.
- If the packaging is damaged, do not use the device
- If the expiry date has passed, do not use the device
- Reuse of a single-use device can also lead to cross-contamination and thus infection of the patient or user
- Using an intraocular lens that is not sized for the intraocular injection system may scratch the lens and reduce its performance.
- Damaged or defective devices must not be used.
- The devices must not be modified or treated.
- The device must be handled with care

MODE OF USE

❶ 

❷ 

❸ 

❹ 

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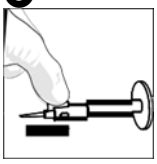
❻ 

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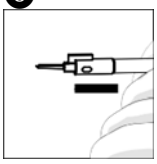
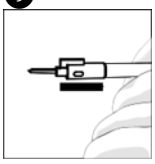
❽ 

❾ 

- Open the sterile barrier system.
- Pour the contents onto the sterile field.
- Open the cartridge packaging.

❶ - Lubricate the inner part of the cartridge with a little sterile viscoelastic ophthalmic solution.
❷ - Place the IOL, anterior side up, in the middle of the cartridge loading chamber.
❸ - Once properly positioned, fold the lens by gently closing the cartridge shutters. Ensure that the LIO is not wedged between the cartridge shutters.

Variant without reamer	Variant with reamer
❻ - Load the cartridge onto the injector	❹ - Use the MDJ pusher and gently push the IOL into the cartridge cylinder. ❺ - Gently remove the MDJ Reamer. ❻ - Load the cartridge onto the injector.

❼ - Lock the injection system by turning the cartridge clockwise
❽ - Gently push the plunger until the blue silicone tip is in contact with the IOL.
Continue to squeeze the plunger until the IOL is positioned in the cannula. There should be no resistance
ATTENTION - In case of resistance, DO NOT USE the system and discard it.

❾ Release the piston, it should return to its original position.
CAUTION - If the plunger does not return to its original position DO NOT USE the system and discard it (the IOL may be blocked and the system)

Insert the cannula into the incision.
Slowly implant the IOL into the capsular bag.
Ensure that the IOL unfolds correctly and is positioned correctly in the capsular bag.

ADVERSE EFFECTS

It is the surgeon's responsibility to provide the patient with all the information before the operation, including the following risks:

- aches and pains
- allergy to any component of the material mentioned on the product label.
- delayed healing, ...
- infection,
- Inflammation

These side effects may lead to a new operation or revision.

IMPORTANT INFORMATION FOR THE SURGEON :

Any serious accident occurring in connection with the device must be notified to the manufacturer and to the competent authority of the Member State in which the user or patient is established.

PACKAGING AND STERILISATION

The information on the label of the device ensures the traceability of its manufacture.
CARTINJECT is sterilised with ethylene oxide.

STERILE DEVICE

- The perfect closure of the packaging elements (blisters and lids) and the integrity of the whole should be checked before using the devices.
- Do not use a product if the packaging is damaged or the tamper-evident label is broken.
- The device can never be resterilised by any method. Re-sterilisation changes the characteristics of the device and its performance.
- The control tablet on the outer packaging, confirming sterilisation, should be green in colour in the case of ethylene oxide (EO) sterilisation. This colour may be affected by poor storage conditions: heat, humidity, light, etc. In any case, a tablet that is yellow in colour before sterilisation may indicate a non-sterile product and, in this case, the product should be returned. Desterilised devices are not accepted for return. The expiry date is indicated on the device label.
- Do not reuse a device, re-sterilization changes the characteristics of the device and its performance. Reuse without sterilisation poses a risk of infection to patients or users.

STORAGE CONDITIONS

Store in a dark place at room temperature. Keep dry.

DISPOSAL OF THE DEVICE

After use, the intraocular injection system should be disposed of as contaminated waste.

DATE OF FIRST EC MARKING: CARTINJECT - 2003

Notice: Cartinject
Ref: Cartinject_eifu-rev O_DRAFT
Date: 06/03/2023

Meaning of the symbols :

	Manufacturer
	Consult the instructions for use
	Attention
	Sterilised by ethylene oxide
	Do not use if packaging is damaged
	Do not reuse
	Do not resterilize
	Batch code
	Catalogue reference
	Use-by date
	Unique device identifier
	Unique sterile barrier system with protection system inside
	Keep away from light
	Fears moisture
CE 1639	Notify Body