DRAFT_PROJECT NOTICE

Ref : Loadinject_eifu-rev O_DRAFT

LOADINJECT

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

DESCRIPTION

The LOADINJECT is a intraocular injection system consisting of an injector with a preloaded cartridge.

Reference	Basic UDI
LOADINJECT	376034321IOLINJECT

LOADINJECT is supplied sterile and is for single use only.

MATERIALS CONSTITUTING THE DEVICE

Injector :

- Polycarbonate for the injector
- Polyacetal for the piston
- Implantable silicone for the piston tip

Cartridge :

- Polypropylene

COMPATIBILITY BETWEEN PROVISIONS

SKU	Product designation Finished (trade name)	Size Incision (mm)	Lens Intraocular
L1.8M11	Loadinject 1.8	1.8 mm	LIO MICS (micro surgery lens) only
L1.8M22	Loadinject 1.8 curved	1.8 mm	LIO MICS (micro surgery lens) only
L2.0M11	Loadinject 2.0	2.0 mm	LIO MICS (micro surgery lens) only
L2.0M22	Loadinject 2.0 curved	2.0 mm	LIO MICS (micro surgery lens) only
L2.2M11	Loadinject 2.2	2.2 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
L2.2M22	Loadinject 2.2 curved	2.2 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
L2.4M11	Loadinject 2.4	<2.4 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs
L2.4M22	Loadinject 2.4 curved	<2.4 mm	Soft hydrophobic acrylic IOLs Standard hydrophilic acrylic IOLs

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
- LOADINJECT 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

Open the sterile barrier system.
Pour the contents onto the sterile field.

❶ - Lubricate the inner part of the cartridge (cone and loading chamber) with sterile viscoelastic ophthalmic solution.

❷ - Place the IOL, anterior side up, on the viscoelastic solution deposited in the loading chamber. Position the haptics against the optic and then fit the front of the IOL into the conical part of the cartridge. The IOL must not be in contact with the blue sleeve.

❸ - Once properly positioned, carefully close the cartridge cover until it clicks into place.

❹ - For LOADINJECT 1.8/2.2/2.4 models, Insert the cannula of the viscoelastic solution syringe inside the hole present on the cartridge cover and fill the chamber to lubricate the inside of the cartridge.

❺ - 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.

❻ - Insert the cannula into the incision without rotating the injector (flat injection), up to the stop of the cannula located between 3 and 5 mm approximately depending on the LOADINJECT 1.8/2.2/2.4 models.

For LOADINJECT 2.0 Insert the cannula into the incision until it reaches the barrel stop at about 3 mm, turn the system 90° to the right.

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.
LOADINJECT 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 with a damaged package or broken tamper-evident label.
- 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 altered 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.

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: LOADINJECT - 2014

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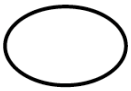
Date: 06/03/2023

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

UDI	Unique device identifier
	Single sterile barrier system
	Keep away from light
	Fears moisture
CE 1639	Notified body - CE marking