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ISO13485 Registered Company

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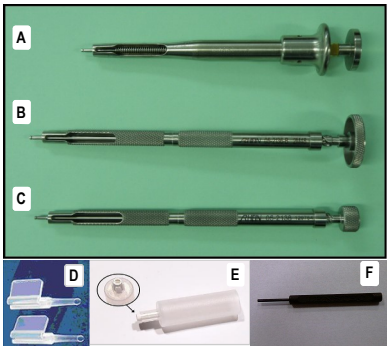
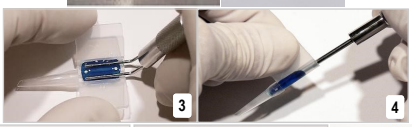
INSTRUCTIONS FOR USE
LENSTEC LC INJECTION SYSTEM





STERILE EO

PKI06 Rev 7

INSTRUCTIONS FOR USE
LENSTEC LC INJECTION SYSTEM

INDICATION FOR USE

Lenstec's LC Injection System is intended for use in implantation of the Softec HD, Softec I, Softec HDO, Softec HDM and any approved IOL in which the labelling specifies use of this injector(s) to insert the lens into the capsular bag following extracapsular extraction.

DESCRIPTION

The system consists of the following components:

- **Titanium Injector I-9011S (see Fig A)**

The syringe type injector is intended to be used with the following cartridges: LC16, LC1620, LC2420, Cart45S, Cart20S and CartM**.** It is used to inject the intraocular lens through an incision into the capsular bag. The injector is manufactured from titanium and is reusable (following decontamination, inspection and sterilization). The injector is supplied unsterile and must be cleaned, inspected and sterilized prior to initial use.

- **Titanium Injector I-9012 (see Figure B); I-9012FS (see Fig C)**

The syringe type injector is intended to be used with the following cartridges: Cart45S, Cart20S and CartM. It is used to inject the intraocular lens through an incision into the capsular bag. The injector is manufactured from titanium and is reusable (following decontamination, inspection and sterilization). The injector is supplied unsterile and must be cleaned, inspected and sterilized prior to initial use.

- **LC/Cart cartridges (see Fig D)**

The sterile single use cartridges are used to fold the intraocular lens prior to implantation. The LC16, LC1620, Cart45S and Cart20S cartridges have a tip diameter of 1.6 mm and are packaged sterile. The LC2420 cartridge has a tip diameter of 2.4 mm and is packaged sterile. The CartM cartridge has a tip diameter of 1.7 mm and is packaged sterile. These should be safely discarded after use as medical waste.

- **Silicone cushion (see Fig E)**

A silicone cushion, which is supplied with each cartridge, is used to provide a cushion when injecting intraocular lenses. The tip is sterile and intended for single use and should be safely discarded after usage as medical waste.

- **Lens Loader (see Fig F)**

The lens loader is used to assure proper placement of the intraocular lens into the cartridge slot. The loader is supplied unsterile and must be cleaned, inspected and sterilized prior to initial use.

HOW TO USE THE LENSTEC CARTRIDGE

PREPARATION

1. Prior to usage, assure that the titanium injector and lens loader have been properly cleaned/decontaminated/inspected and sterilized. Once sterile, they may be transferred into the operative sterile field.
2. In the sterile field, peel back the Tyvek™ cover and place the cartridge and silicone cushion (encased by the silicone cushion holder) on the sterile operating room tray.

LOADING THE LENS INTO THE CARTRIDGE / INJECTOR ASSEMBLY

To ensure that the intraocular lens is folded and works effectively and consistently, it is essential to follow the correct procedure when loading the lens in the cartridge.

The following is a step-by-step guide that explains how to load the injector.

Note: *A blue lens was used in the instructions for use for visibility purposes only.*

1. ***For Cart series cartridges:*** Open the cartridge flaps and rinse each side of the chamber with saline. (See Fig 1).
2. ***For LC series cartridges:*** Open the cartridge flaps and inject each side of the chamber with viscoelastic. (See Fig 1).
3. Making sure that the plunger tip is exposed; use the applicator to fix the silicone cushion onto the plunger tip. Apply a small amount of viscoelastic to the silicone cushion, and then pull the plunger back. (See Fig 2).
4. Remove the lens from its vial. Holding the flaps of the cartridge open slightly wider than 90°, place the lens in the cartridge as you would want it in the eye. Place a partially open pair of sterile, angled forceps (i.e. McPherson, Bechert etc) over the whole lens (including the haptics); press firmly to make sure that the optic edges are placed under the edge of the flaps. As you do this, allow the flaps to close 1/3 to 1/2 way. (See Fig 3).
   NOTE: IT IS IMPERATIVE THAT THE IOL BE INJECTED INTO THE EYE WITHIN TWO MINUTES OF REMOVAL FROM THE SALINE FILLED VIAL. DUE TO THE HYDROPHILIC NATURE OF THE LENSES, EXTENDED PERIODS OF TIME OUTSIDE OF THE SALINE WILL CAUSE THE LENSES TO DEHYDRATE AND SUBSEQUENTLY BECOME DAMAGED DURING THE INJECTION PROCESS.
5. Using an appropriate instrument, ensure that the haptics are in the correct position and secure in the cartridge. Ensure that the haptics are not twisted. Close the cartridge flaps swiftly and look at the cartridge chamber from the side and check that no part of the optic or haptics are caught in the flaps. *It is imperative to ensure that the trailing haptic is 'tucked' within the boundaries of the chamber prior to injection.* Place the lens loader's blunt end into the back of the chamber, while the flaps are still closed, and advance the lens from the chamber to the barrel (See Fig 4). Ensure that the lens loader is advanced to its farthest depth, so that the lens is in the cartridge tip (nosecone). The cartridge is now ready to load in the injector. .
   NOTE: FAILURE TO ENSURE THE LENS HAPTIC OR OPTIC IS PROPERLY PLACED IN THE CARTRIDGE CAN LEAD TO DAMAGE DURING INJECTION/IMPLANTATION.
6. Ensuring that the plunger is retracted as far as possible, place the cartridge barrel first into the housing and push it in as far as it will go (See Fig 5).
7. Depress the injector plunger so that the silicone cushion fits into the back of the cartridge chamber and advance it forward until you can just see the tip in the barrel. (See Fig 6)

8. The injector is now ready to use (See Fig. 7).

WARNINGS

1. Clean, inspect and sterilize the injector and lens loader before initial use and prior to subsequent use.
2. The cartridges are intended for 'Single Use'. Do not resterilize or reuse.
3. The cartridges are sterile unless the external pouch is damaged. If this packaging is damaged, do not use.
4. Discard used cartridges as medical waste containers.
5. Do not use aggressive detergents or any kind of abrasive. Never use balanced salt solution for rinsing the instruments.
6. The LC Injection System is intended for use with only the intraocular lenses with which it is validated.
7. Proper surgical procedure is the responsibility of the individual surgeon. The surgeon must determine the suitability of any particular procedure based upon his/her medical training and expertise.

CONTRAINDICATIONS

- None known

CLEANING INSTRUCTIONS

MANUAL

- Prior to initial use and immediately after every use thereafter, soak the injector and lens loader devices in warm utility water (30-45 °C) for a minimum of five (5) minutes.
- At the end of the five (5) minutes, and while submerged in the soak water (warmed utility water), manipulate the plunger, depending on the injection mechanism, i.e. push or twist, by simulated plunging, the full length of the device at least ten (10) times to loosen up the soil in the lumen.
- Next, while submerged in soak water, scrub the device and its crevices with a soft-bristled brush. Repeat this step with the plunger inserted fully down the device as well as with the plunger in the fully retracted position.
- Visually inspect the device and confirm the absence of gross soil debris. If gross soil debris remains, re-immerse the device in the soak water and continue scrubbing the device with the soft-bristled brush until confirmation that it is visually free of gross soil debris.

SONICATION

- Submerge the injector and lens loader devices in a sonicating waterbath of critical water (100 mL).
- Incubate the devices under sonication for a minimum of 10 minutes.

RINSING

- Remove the injector and lens loader devices from the sonicating waterbath and rinse them under running critical water for 30 to 60 seconds. While rinsing, articulate the plunger rapidly back and forth to aid in the elimination of debris from the interior of the syringe.
- Lay the device out to dry with the plunger fully inserted.

NOTE: *Do not use or reuse if wear or damage is apparent. This can include, but is not limited to, discoloration, chipping or material degradation. Be sure to clean any contamination appearing on the device prior to sterilization as this could cause wear or damage to the device(s)*

NOTE: *Should any other type of cleaning method be used, the user must verify its effectiveness prior to sterilization and subsequent use*

STERILIZATION AND RESTERILZATION OF THE INJECTOR

After the device(s) has been properly cleaned, it is recommended that it be sterilized in accordance with one of the following standards:

1. AAMI ST79: 2010 & A1: 2010; A2:2011, A3:2012 & A4:2013 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities"
2. Local national standards

STERILIZATION CYCLE PARAMETERS

UNWRAPPED ITEMS:

1. Gravity displacement vessel: The recommended minimum exposure time and temperature for the injector and lens loader is three (3) minutes at 135°C (270°F), with a load size of three (3) Lenstec reusable surgical instruments in those autoclaves common to healthcare facilities. The recommended dry time is a minimum of 1 minute.
2. NOTE: This validated cycle represents a 'worst case' scenario representing the shortest duration sterilization cycle which effectively sterilizes the instruments. This is also a scenario which is most likely to be used by health care facilities due to the type of equipment most readily available to sterilize surgical instruments. Should any other type of sterilization method or parameters be used (i.e. varying time/temperature combinations, sterilizing items in a wrapped configuration, load size, etc.), the user must verify its effectiveness prior to use.
3. NOTE: Do not resterilize the injector cartridge. The cartridge is a Single Use Only component.

WRAPPED ITEMS (AN FDA CLEARED WRAP SHOULD BE UTILIZED WITH THESE RECOMMENDED CYCLES)

1. Gravity displacement vessel: The recommended minimum exposure times and temperatures validated for the injector and lens loader with a load size of three (3) Lenstec reusable surgical instruments are:
   - Thirty (30) minutes at 121°C (250°F)
   - Fifteen (15) minutes at 132°C (270°F)
2. The recommended dry time is a minimum of 30 minutes.
3. NOTE: This validated cycle represents a 'worst case' scenario representing the shortest duration sterilization cycle which effectively sterilizes the instruments. This is also a scenario which is most likely to be used by health care facilities due to the type of equipment most readily available to sterilize surgical instruments. Should any other type of sterilization method or parameters be used (i.e. varying time/temperature combinations, sterilizing items in a wrapped configuration, load size, etc.), the user must

verify its effectiveness prior to use.

4. NOTE: Do not resterilize the injector cartridge. The cartridge is a Single Use Only component.

SURGICAL PROCEDURE

Proper surgical procedure is the responsibility of the individual surgeon. The surgeon must determine the suitability of any particular procedure based upon his/her medical training and expertise.

WARRANTY AND LIMITATION OF LIABILITY

The manufacturer warrants that reasonable care was used in making this product. The manufacturer shall not be responsible for any immediate or subsequent loss, damage, or expense, which arises directly or indirectly from the use of this product. Any liability shall be limited to the repair or replacement of the injector found to be defective not as a result from improper handling.

Cartridge Compatibility Chart

LC Cartridge Chart				
Cartridge with Silicone Cushion	**IOL**	**Injector**	**Tip Diameter (mm)**	**Lenstec IOL Power Range (D)**
LC16	Softec HD	I-9011S	1.6	+5.0 to +26.0
	Softec I			
	Softec HDM			Softec HDM +5.0 to +36.0

Cart Series Cartridge Chart				
Cartridge with Silicone Cushion	**IOL**	**Injector**	**Tip Diameter (mm)**	**Lenstec IOL Power Range (D)**
Cart45S	Softec HD	I-9011S I-9012 I-9012FS	1.6	+5.0 to +26.0
	Softec I			
	Softec HDO			
CartM	Softec HDM	I-9011S I-9012 I-9012FS	1.7	+5.0 to +36.0

LEGEND

Symbol	Meaning	Symbol	Meaning
	Consult instructions for use	Rx	Prescription use only
	Do not reuse		Lot number
	Use by		Caution. Consult accompanying documents
	Sterilized using ethylene oxide		Temperature limitation