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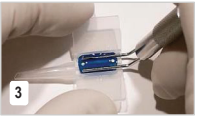
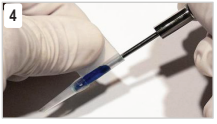
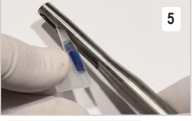
INSTRUCTIONS FOR USE
LENSTEC LC INJECTION SYSTEM







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INSTRUCTIONS FOR USE
LENSTEC LC INJECTION SYSTEM

INDICATION FOR USE

The Lenstec LC Injection System is intended for use in implantation of the Softec HD, Softec I and Softec HD PS model Lenstec IOLs, as well as any indicated for its use in its approved labeling, into the capsular bag following extracapsular extraction.

DESCRIPTION

The system consists of the following components:

- **Titanium Injector I 9011S (See Figure A)**

The syringe type injector is intended to be used with the following cartridges: LC 16, LC 1620 and LC 2420. 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 and sterilization). The injector is supplied unsterile and must be cleaned and sterilized prior to initial use.

- **LC cartridges (See Figure B)**

The sterile, single-use cartridges are used to fold the intraocular lens prior to implantation. The LC 16 and LC 1620 cartridges have a tip diameter of 1.6mm and are packaged sterile. The LC 2420 cartridge has a tip diameter of 2.4mm and is packaged sterile. These should be safely discarded after use as medical waste.

- **Silicone cushion (See Figure C)**

A silicone cushion, which is supplied with each cartridge, is used to prevent the injector plunger from contacting the IOL during injection. The tip is sterile and intended for single use and should be safely discarded after usage as medical waste.

- **Lens Loader (See Figure D)**

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 before initial use and prior to subsequent 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 tip (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. Open the cartridge flaps and inject viscoelastic down each side of the chamber (See Figure 1).
2. 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 Figure 2).
3. Remove the lens from its vial. Holding the flaps of the cartridge open as far as possible, 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 Figure 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.

4. 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 lens or haptics is 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 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 Figure 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.

5. 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 Figure 5).
6. 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 Figure 6).
7. The injector is now ready to use (See Figure 7).

Cartridge Chart				
Cartridge with Silicone Cushion	**IOL**	**Injector**	**Tip Diameter (mm)**	**Lenstec IOL Power Range (D)**
LC 16	Softec HD Softec I Softec HD PS	I-9011S	1.6	+5.0 to +26.0
LC 1620	Softec HD Softec I Softec HD PS	I-9011S	1.6	+5.0 to +26.0
LC 2420	Softec HD Softec I Softec HD PS	I-9011S	2.4	+5.0 to +36.0

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 re-sterilize 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 Lenstec LC Injection System is intended to be used only with the intraocular lenses for which it has been 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)

1. Prior to initial use and immediately following every use thereafter, rinse the injector and lens loader with deionized water and then clean the device and its crevices using a soft surgical/laboratory brush moistened with alcohol. Care should be taken to avoid damage to the extreme tip of both devices.
2. Inspect the instrument(s) under magnification (10x) to check for gross contamination, wear or damage. Do not use or reuse if wear or damage is apparent. This can include, but is not limited to, discoloration, chipping or material degradation.
3. Be sure to clean any contamination prior to sterilization as this could cause wear or damage to the device(s).

NOTE: Should any other type of cleaning method be used (i.e. Ultrasonic, detergent cleaner, etc), 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 AI 2008; A2 2009 "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.
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:

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. 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.

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.

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

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