



## **Sales Information Manual**

**Lenstec, Inc.**  
**1765 Commerce Ave N, St. Petersburg, Florida 33716**  
**Toll Free Phone: 866-LENSTEC (536-7832), Toll Free Fax: 866-536-3040**



## LENSTEC Sales Information Manual Table of Contents

About Lenstec, Inc. ....	3
Company Contact Information .....	4
Product Information .....	5
Consignment Information .....	12
Consignment Agreement .....	13
Order Information .....	15
Order Information Definitions .....	16
Patient Implant Identification Cards .....	16
Fax/E-mail Re-Order Form for IOLs .....	17
Fax/E-mail Re-Order Form for IOLs (additional page).....	18
Product Return Information .....	19
Product Exchange & Refund Policy .....	19
Return Authorization Form .....	20
Inventory Return Form .....	22
IOL Inventory Assessment Information .....	23
Accounting Information .....	24
Customer Contact Information Form .....	25
Lenstec Intraocular Lens Price Agreement .....	26
Lens Loading Instructions for Use .....	27

## About LENSTEC

LENSTEC is a Florida based medical device corporation servicing the global ophthalmic market, with Lenstec products currently available in more than fifty countries. The company designs, manufacturers, and distributes intraocular lens (IOL) implants to treat patients with a range of vision disorders, as well as lens injection systems and other ophthalmic surgical supplies.

Founded in 1992, Lenstec has an established reputation for rapid prototype design and development, and high-quality manufacturing.

### Lenstec Barbados Manufacturing Office

The proprietary lens manufacturing technologies developed by Lenstec enable the company to produce premium lenses with reduced variability and improved surgical predictability.

In addition, most of the micro-precision lathes, mills, polishing equipment, silicone molds, processing equipment, and processes are designed and built in-house by Lenstec's engineering staff. Approximately 12 percent of all IOLs sold worldwide are produced on Lenstec-designed equipment sold to other manufacturers.

Lenstec currently has offices in Florida and the United Kingdom, and a state of the art manufacturing facility in

### Lenstec Headquarters, St Petersburg, Florida



Barbados, designed by Lenstec to exceed all medical device standards and with the capacity to meet future demand for Lenstec products. Lenstec first received the CE Mark in 1997, and the new facility was certified by British Standard Institution upon completion.

At Lenstec, we continuously strive to improve vision possibilities through research, testing, and a partnership with the world's leading ophthalmologists. We welcome your interest in the company and any questions you may have about our products and services or opportunities to partner with us.



**Lenstec is an ISO 13485 Registered company manufacturing CE and FDA products.**



FM 38446

## **LENSTEC Contact Information**

**LENSTEC, INC.  
1765 Commerce Avenue North  
Saint Petersburg, Florida 33716**

**Toll Free Phone: 1-866-LENSTEC (1-866-536-7832)  
Toll Free Fax: 866-536-3040**

**E-mail: [orders@Lenstec.com](mailto:orders@Lenstec.com)**

## LENSTEC Product Information

**Softec HD: High Definition Intraocular Lens in .25 diopter increments from +15.00 to +25.00**

Optic Size:	5.75mm
Optic Type:	Equal Conic Bi-aspheric
Length:	12.00 mm
Haptic Style:	Modified C
Angulation:	0 Degrees
Construction:	1 Piece
Positioning Holes:	0
Optic Material:	Acrylic Hydrophilic (26% Water Content)



### Constants (Optical Interferometry):

Immersion:	A = 118.3
SRK/T:	A = 118.3
Holladay-1:	sf = 1.39
Hoffer Q:	pACD = 5.14

The A-Constant and ACD values printed are estimates only. It is recommended that the surgeon determine his or her own values based on their individual clinical experience.

Diopter Range:	Whole: + 5.0 to +36.0
	Half: +10.5 to +29.5
	Quarter: +15.00 to +25.00



U.S. Patent No. 7,350,918 B2 April 1, 2008

## LENSTEC Product Information

**Softec HDO - Oval, High Definition Intraocular Lens in .25 diopter increments from +15.00 to +25.00**

<b>Optic Size:</b>	5.75 mm x 6.5 mm
<b>Optic Type:</b>	Equal Bi-aspheric
<b>Length:</b>	12.5 mm
<b>Haptic Style:</b>	Modified C
<b>Angulation:</b>	0 Degrees
<b>Construction:</b>	1 Piece
<b>Positioning Holes:</b>	0
<b>Optic Material:</b>	Acrylic Hydrophilic (26% Water Content)



**Constants (Optical Interferometry):**

<b>Immersion:</b>	A = 118.54
<b>SRK/T:</b>	A = 118.54
<b>Holladay-1:</b>	sf = 1.48
<b>Hoffer Q:</b>	pACD = 5.28

The A-Constant and ACD values printed are estimates only. It is recommended that the surgeon determine his or her own values based on their individual clinical experience.

<b>Diopter Range:</b>	<b>Whole:</b> + 5.0 to +36.0
	<b>Half:</b> +10.5 to +29.5
	<b>Quarter:</b> +15.00 to +25.00



# LENSTEC Product Information

## **Softec HDM- High Definition, Micro-Incision Intraocular Lens in .25 diopter increments from +15.00 to +25.00**

<b>Optic Size:</b>	5.75mm
<b>Optic Type:</b>	Equal Conic Bi-aspheric
<b>Length:</b>	12.00 mm
<b>Haptic Style:</b>	Modified C
<b>Angulation:</b>	0 Degrees
<b>Construction:</b>	1 Piece
<b>Positioning Holes:</b>	0
<b>Optic Material:</b>	Acrylic Hydrophilic (26% Water Content)



### **Constants (Optical Interferometry):**

<b>Immersion:</b>	A = 117.80
<b>SRK/T:</b>	A = 117.80
<b>Holladay-1:</b>	sf = 1.11
<b>Hoffer Q:</b>	pACD = 4.85

The A-Constant and ACD values printed are estimates only. It is recommended that the surgeon determine his or her own values based on their individual clinical experience.

<b>Diopter Range:</b>	<b>Whole: + 5.0 to +36.0</b>
	<b>Half: +10.5 to +29.5</b>
	<b>Quarter: +15.00 to +25.00</b>



## LENSTEC Product Information

### Softec I - One-Piece Acrylic Foldable Intraocular Lens

Optic Size:	5.75mm
Optic Type:	Equiconvex
Length:	12.00 mm
Haptic Style:	Modified C
Angulation:	0 Degrees
Construction:	1 Piece
Positioning Holes:	0
Optic Material:	Acrylic Hydrophilic (26% Water Content)

#### Constants (Optical Interferometry):

Immersion:	A = 118.3
SRK/T:	A = 118.3
Holladay-1:	sf = 1.39
Hoffer Q:	pACD = 5.14



The A-Constant and ACD values printed are estimates only. It is recommended that the surgeon determine his or her own values based on their individual clinical experience.

Diopter Range:	Whole: + 5.0 to +36.0
	Half: +10.5 to +29.5





# LENSTEC Product Information

## ClearView 3 - One-Piece Acrylic Segmented Bifocal Intraocular Lens

Optic Size:	5.75mm
Optic Type:	Refractive, aspheric segment bifocal; +3.00 at IOL plane
Length:	11.00 mm
Haptic Style:	Closed Loop, Modified Plate
Angulation:	0 Degrees
Construction:	1 Piece
Optic Material:	Acrylic Hydrophilic (26% Water Content)



### Constants (Optical Interferometry):

Immersion:	A = 118.0
Holladay-1:	sf = 1.22
Hoffer Q:	pACD = 4.97
Barret	LF=1.36
Haigis	a0=0.537 a1=0.333 a2=0.126

The A-Constant and ACD values printed are estimates only. It is recommended that the surgeon determine his or her own values based on their individual clinical experience.

Diopter Range:	Whole: +15.0 to +30.0
	Quarter: +15.0 to +25.0
	Half: +15.5 to +30.0



**INJECTION SYSTEM**



**I9011S – Push Titanium Injector**

**I-9012 – Large-Knob Threaded Titanium Injector**

**I-9012FS – Small-Knob, Fine-Threaded Titanium Injector (Large Knob available)**

## LENSTEC Product Information

### CARTRIDGES AND DISPOSABLE INJECTION SYSTEM



**LC16, CART45S – Single use Micro-incision cartridge, 45° bevel and silicone tip, designed to fit comfortably through a 2.7 incision, 10 / box**

**CARTM – Single use Micro-incision cartridge, 45° bevel and silicone tip, designed to fit a Softec HDM IOL comfortably through a 2.2 mm incision size - 10 / box**

**LC1645SI – Single use disposable injector with Micro-incision cartridge, 45° bevel and silicone tip, designed to fit comfortably through a 2.7 incision -10 / box (the above also available in 2.4 mm for larger IOLs – LC24)**

## Consignment Information

On the following page is your consignment agreement with LENSTEC

Please note the main points listed below:

- LENSTEC pays the shipping for the initial consignment. The Customer pays for the shipping of replacement lenses.
- The Customer assumes responsibility for the safe storage and handling of the consignment. The IOLs must be stored in dry conditions between 0°C (32°F) and 45°C (113°F), and the lenses should be handled carefully; rough handling or excessive handling may damage the lens.
- The Customer is responsible for the quantity and value of consigned lenses.
- A physical inventory of the consignment will be conducted twice per year. If the inventory count is less than what our records reflect, the Customer agrees to provide implant information and a purchase order for payment of implanted or unaccounted for lenses.
- Payment shall be made net thirty (30) days from the invoice date.
- The Customer agrees not to sell, trade, borrow, or exchange lenses with any other entity without prior arrangements approved by LENSTEC
- Any lens to be returned (i.e., exchange of consignment, overstock, expired etc.) must be accompanied by an Inventory Return (IR) form which may be obtained at [www.Lenstec.com/customers](http://www.Lenstec.com/customers). The shipping label, which is at the customer's expense, must be affixed to the outside of the carton and the completed Inventory Return Form enclosed. Any credit for purchased lenses or to your consignment for lenses will not be given until product is received.
- It is possible to change the total quantity of lenses on consignment by contacting your sales representative.
- FIFO (First in, first out) inventory usage is encouraged in order to avoid having expiring lenses.
- As replacement lenses are ordered, Lenstec will include a Consignment Transfer document and packing slip .
- An initial consignment order will not be shipped until the following "Implant Consignment Agreement" is signed and a copy is sent to LENSTEC.

## IMPLANT CONSIGNMENT AGREEMENT

This Implant Consignment Agreement is made the \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, by and between Lenstec, Inc., ("LENSTEC") at 1765 Commerce Avenue North, Saint Petersburg, Florida 33716, and \_\_\_\_\_ ("CUSTOMER") at \_\_\_\_\_.

**LENSTEC and CUSTOMER agree as follows:**

### SECTION 1. PRODUCT CONSIGNED

The number of IOLs and instruments (namely, injector) allowed in a CUSTOMER's consignment is directly related to the estimated number of LENSTEC implants performed. The size of the consignment may be reviewed and adjusted from time to time at LENSTEC's discretion. It is understood and agreed that the CUSTOMER is under no obligation to purchase a certain volume of IOLs.

### SECTION 2. SHIPPING AND HANDLING

LENSTEC will pay the shipping and handling charges related to the initial consignment. CUSTOMER will pay for any future shipping charges. All shipping related claims for shortages, shipping errors, lost, stolen or damaged lenses must be made to LENSTEC within thirty (30) days of shipment.

### SECTION 3. TITLE

While title to consignment lenses will remain with LENSTEC until implantation, the CUSTOMER assumes total responsibility for the safe storage of the consignment and agrees to be responsible for the quantity and value of consigned lenses. The IOLs must be stored in dry conditions between 0°C (32°F) and 45°C (113°F), and the lenses should be handled carefully; rough handling or excessive handling may damage the lens. CUSTOMER will be responsible for the lens charges resulting from damage to or loss of consignment lenses while the lenses are in the CUSTOMER's care, custody, and control. As lenses are replaced in the consignment, it is understood that the consignment lenses may differ from those originally shipped.

### SECTION 4. IMPLANT INVENTORY MAINTENANCE

The CUSTOMER agrees to e-mail (orders@Lenstec.com), fax (1-866-536-3040), or phone (1-866-536-7832) to the LENSTEC CUSTOMER Service Department the implants used from the consignment inventory and to order lens replacements. The CUSTOMER agrees to allow any Lenstec Inc. representative access to the consignment inventory. A LENSTEC representative will conduct a physical inventory twice per year of the consignment stock. If the total quantity of consigned lenses be less than what Lenstec Inc.'s records reflect, the CUSTOMER agrees to provide the representative with implant information and a Purchase Order for payment of implanted or unaccounted for lenses. LENSTEC has the right to reduce the inventory to return the consignment to a reasonable level based on inventory usage. Lenstec Inc. reserves the right to request the return of any unused lenses.

### SECTION 5. IMPLANT BILLING AND INVOICE TERMS

The initial consignment of lenses will be accompanied by a packing sheet specifying the lenses consigned. When lenses are implanted and serial numbers and diopters are reported for billing, an invoice will be based on the negotiated price of the lens, namely:

Softec HD	\$_____ per lens	ClearView 3	\$_____ per lens
Softec HDO	\$_____ per lens	Softec HDM	\$_____ per lens
Softec I	\$_____ per lens		

A consigned replacement will be shipped unless otherwise noted.

Payment shall be made net thirty (30) days from the invoice date. Past due invoices may be assessed a monthly service charge at the lower of 1.5% per month or the highest rate permitted by law. In the event of nonpayment of the invoices within the terms specified, LENSTEC reserves the right to refuse to deliver and/or terminate the Consignment Agreement.

### SECTION 6. CUSTOMER USE OF THE CONSIGNMENT

The CUSTOMER agrees as to each lens style, power, and size to use FIFO, namely in the order in which delivered, with those lenses first delivered being used before subsequently delivered lenses. The CUSTOMER agrees not to sell, trade, borrow, or exchange lenses with any doctor, hospital, or any other entity without prior contractual arrangements approved by LENSTEC

### SECTION 7. RETURNS, REPLACEMENTS, EXCHANGES

LENSTEC agrees to accept all consigned lenses for return at the termination of this agreement provided that the lenses are in their original, sealed packages and are accompanied by a completed Lenstec Inventory Return Form. Customer is responsible for shipping.

Lenstec Inc. will accept lenses for exchange due to packages being opened or for lenses with sterility dates close to expiration (within 6 months) or lenses that have expired. LENSTEC agrees to accept any unopened lens consignment for exchange for a

lens of any style, power, or size. Any lens to be returned (i.e. exchange of consignment, expired, etc.) must be accompanied by an Inventory Return (IR) form which may be obtained by visiting <http://www.Lenstec.com/customers>. The customer is responsible for shipping. Any lens which had contact with the patient or the subject of a possible complaint must be returned with a completed Return Authorization (RA) Form. The Lenses which have contact with the patient should be called into Customer Service for an RA# and prepaid label must be affixed on the outer carton, and if there has been patient contact, the lenses must be sent back under biohazard label. Once a return is received at Lenstec and is processed, a credit to the account or to the consignment will be issued. No credits are issued without receipt of product and completed Return Authorization form.

All lenses that become opened and not used without patient contact will be retained and returned to Lenstec accompanied by a completed Return Authorization (RA) form. No lens shall be destroyed in any way at your facility. The RA form may be obtained at <http://www.Lenstec.com/customers>. Customer is responsible for return postage. A replacement will be sent upon receipt of the lens, if one is requested, or the Customer may contact Lenstec Customer Service to add to your facilities consignment. Customer is responsible for shipping charges of replacement lenses.

**SECTION 8. ADJUSTMENTS OR TERMINATION OF CONSIGNMENT AGREEMENT**

It is possible to change the total quantity of lenses on consignment by contacting Lenstec Customer Service. LENSTEC or the CUSTOMER may terminate this agreement by giving thirty (30) days advance notice in writing to the other party at the address specified in this agreement. Upon notice of termination, the CUSTOMER agrees to return all consignment lenses within fourteen (14) days. LENSTEC will invoice all consignment lenses not returned. The basis for these charges is agreed to be the current prices in effect on the date of termination of this agreement.

**SECTION 9. TAXES**

Prices quoted do not include applicable sales or use taxes. CUSTOMER shall be responsible for and will pay to LENSTEC all sales and use taxes resulting from a consignment or sales under this agreement.

In those states where intraocular lenses are subject to sales and use taxes, the CUSTOMER must supply a valid Resale or Exemption certificate, if applicable, in order for LENSTEC not to charge sales and use tax.

**SECTION 10. GOVERNING LAW; CONTRACT SCOPE**

This agreement shall be governed by the laws of the state of Florida. It is agreed by you, the CUSTOMER, and LENSTEC that this written agreement constitutes the total agreement between the parties regarding the subject matter hereof. No verbal agreement will be recognized. Representatives have no authority to alter or amend the terms and/or the provisions of this agreement. Any amendments or alterations require the written approval of the Vice President of Sales & Marketing.

**SECTION 11. Instrument Consignment:**

Client agrees to consign the following number of instruments, with a cost of \$600.00 per injector if not returned to Lenstec.

Instrument Set:	Number of Instruments to consign:
I-9011S Push Injector & Lens Loader II	_____
I-9012FS Fine Screw Twist Injector & Lens Loader II	_____
I-9012 Twist Injector & Lens Loader II	_____

**CUSTOMER HOLDING CONSIGNMENT**

**BILLING INFORMATION (if different from shipping)**

\_\_\_\_\_  
Account Name

\_\_\_\_\_  
Account Name

\_\_\_\_\_  
Shipping Address

\_\_\_\_\_  
Billing Address

\_\_\_\_\_  
City, State, Zip

\_\_\_\_\_  
City, State, Zip

\_\_\_\_\_  
Customer Signature                      Date

\_\_\_\_\_  
Signature of Lenstec Representative

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Title

Return signed agreement to:      Lenstec, Inc.  
1765 Commerce Ave N  
St. Petersburg, FL 33716

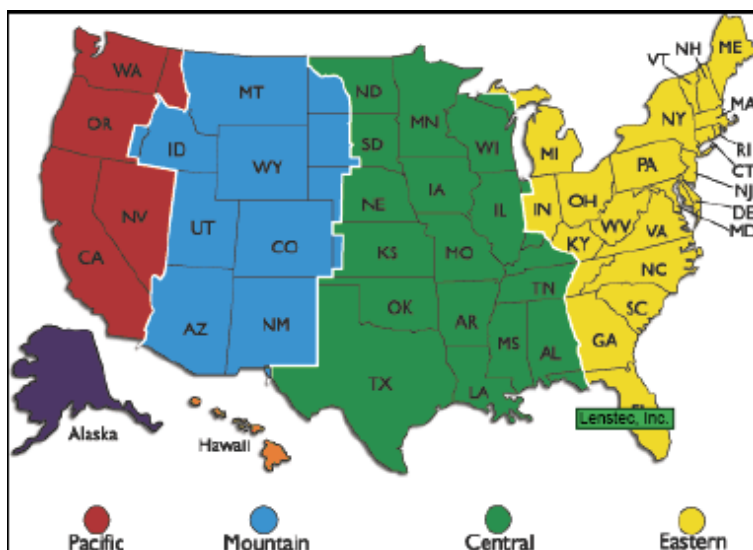
## LENSTEC Order Information Definitions

Orders can be faxed, e-mailed, or phoned to our Customer Service Department.

- ✓ **Faxed orders:** 1-866-536-3040, see fax form in this manual
- ✓ **E-mail orders:** [orders@Lenstec.com](mailto:orders@Lenstec.com), can use fax form to scan & e-mail
- ✓ **Call-in orders:** 1-866- LENSTEC (536-7832), ask for Customer Service

Please note the following items on your order:

- ✓ **Today's date , required delivery date, and surgery date**
- ✓ **Lenstec Sales Representative's name**
- ✓ **Account name and address and name of person placing the order**
- ✓ **Note if order is "Bill and Replace", "Add to Consignment", "Bill Only", or Direct Purchase" (see definitions, next page)**
- ✓ **Standard shipping is 2<sup>nd</sup> day, so please note if you prefer a different option.**
- ✓ **Express orders received by 5:00 PM EST (Eastern Standard Time) and Ground orders received by 3:30 PM EST will be shipped the same business day via Federal Express.**



## LENSTEC Order Information Definitions

### “Bill and Replace”

- The lenses used in surgery are from a consignment with LENSTEC.
- In order to replace those lenses to your consignment, the lenses that were implanted must be reported to LENSTEC.
- The implanted lenses will be billed to your facility.
- Replacement lenses of the same model and diopter will be shipped to your facility for your consignment.

### “Bill Only”

- The lenses used in surgery are from a consignment with LENSTEC.
- If you mark the order “bill only,” the implanted lenses will be billed to your facility and not replaced to your consignment.

### “Add To Consignment”

- Under special circumstances, lenses outside your consignment range may be added to your consignment for a specific surgery or if a need exists to expand your consignment in a particular diopter or range of diopter.

### ”Direct Purchase”

- Lenses and other products that are ordered from LENSTEC and billed at the time of shipment.

## Patient Implant Identification Cards

As each Lenstec Intraocular Lens box includes a Patient Implant Identification Card to complete, please utilize the Prepaid Business Reply Envelopes included with each order shipment to mail the completed cards back to Lenstec.

The data from these cards is used in the event Lenstec needs to contact your facility regarding a particular lens or series of lenses, and is also used to reconcile your account to ensure all implanted lenses have been reported to Lenstec for billing.

Please contact Lenstec Customer Service if you should need more envelopes.





**LENSTEC Toll Free Fax/E-mail Re-Order Form**

**Fax To: 1-866-536-3040 or E-mail To: orders@Lenstec.com**

Order Date: \_\_\_\_\_ Required Delivery Date: \_\_\_\_\_ Surgery Date: \_\_\_\_\_

Account #: \_\_\_\_\_ P.O. #: \_\_\_\_\_ Lenstec Sales Rep: \_\_\_\_\_

Account Name: \_\_\_\_\_ Name of Person Ordering: \_\_\_\_\_

Account Address: \_\_\_\_\_ City, State, Zip: \_\_\_\_\_

Type of Order:  Bill & Replace  Bill Only  Add to Consignment  Direct Purchase

Shipping Method:  Ground  Express Saver  2<sup>nd</sup> Day  Standard Overnight

Priority Overnight  First Overnight

**IOL Re-Order Form**

**Surgeon's Name: Dr. \_\_\_\_\_**

Place IOL Label Here	Place IOL Label Here
Place IOL Label Here	Place IOL Label Here
Place IOL Label Here	Place IOL Label Here
Place IOL Label Here	Place IOL Label Here
Place IOL Label Here	Place IOL Label Here

Page \_\_\_\_ of \_\_\_\_ No. of Boxes of Cartridges needed with this reorder: \_\_\_\_\_

Fax to: 1-866-536-3040 or E-mail to: [orders@Lenstec.com](mailto:orders@Lenstec.com)

Acct #: \_\_\_\_\_ Order Date: \_\_\_\_\_ Surgeon's name: \_\_\_\_\_ Page \_\_\_ of \_\_\_\_\_

Place IOL Label Here	Place IOL Label Here
Place IOL Label Here	Place IOL Label Here
Place IOL Label Here	Place IOL Label Here
Place IOL Label Here	Place IOL Label Here
Place IOL Label Here	Place IOL Label Here
Place IOL Label Here	Place IOL Label Here
Place IOL Label Here	Place IOL Label Here
Place IOL Label Here	Place IOL Label Here

No. of Boxes of Cartridges needed with this reorder: \_\_\_\_\_

## Return of Unopened Product to Lenstec

Please follow the instructions to return any unopened product to LENSTEC:

- ✓ Complete an Inventory Return Form (IR) which may be obtained on page 22 or by visiting [www.Lenstec.com/customers](http://www.Lenstec.com/customers).
- ✓ Ship the item(s) to be returned and the completed IR Form to the following address to Lenstec. Return shipping is at the customer's expense. Lenses should be returned to Lenstec Returns, 1765 Commerce Ave N, St Petersburg, FL 33716. Please note the Return and Refund Policy on bottom of this page.

## Return of Opened-and-not-Used Lenses or Lenses which Have Contact with the Patient

When a Lens has been opened and not used, has had contact with the patient, or is the subject of a complaint or adverse event, the lens should be retained and returned to Lenstec for proper determination and/or disposal:

- 1) Complete the **Return Authorization (RA) Form** found on Page 20 or may also be downloaded at [www.Lenstec.com/customers](http://www.Lenstec.com/customers). Please indicate if you would like a replacement lens or contact Customer Service to add the lens to consignment.
- 2) Return the completed RA Form along with the device and any packaging to LENSTEC, 1765 Commerce Avenue North, St Petersburg, FL 33716.
- 3) If the device had contact with the patient or is the subject of a complaint or adverse event, please contact Lenstec Customer Service for a Return Authorization Number and Prepaid Return Label.

## LENSEC Return and Refund Policy

As of September 1, 2015, lenses directly purchased through Lenstec may be returned within 30 days from the purchase date for credit to the account. Credits may be used for open invoices and are not refundable.

Both opened and not used and expired lenses which were directly purchased are not eligible for credit. Customer is responsible for return shipping. Any lenses purchased as part of a bulk purchase arrangement at a reduced price are not eligible for return, exchange, or credit.

# CUSTOMER RETURN AUTHORIZATION FORM

**PLEASE USE THIS FORM FOR OPENED DEVICES ONLY WHICH INCLUDES:  
OPENED & NOT USED, LENSES WITH PATIENT CONTACT OR ISSUE WITH THE LENS.  
UNOPENED OVERSTOCK OR EXPIRED DEVICES SHOULD BE REPORTED ON INVENTORY RETURN FORM**

Contact Person: \_\_\_\_\_ Date: \_\_\_\_\_

## CUSTOMER DETAILS

Company Name:				
Account #				
Address				
City	State:		Zip Code:	
Telephone No:		Fax No:		

**\*Complete Page 2 for each device with Patient Contact and call Lenstec Customer Service for a Return Authorization Number. No RA# needed for other returned devices.**

## ITEM DETAILS

Device Serial No.	Patient Contact or Issue with the IOL (Y/N)* <small>Complete Pg. 2 for each device</small>	Model/Diopter	Injector (Cartridge) Type & Batch#	Doctor	Reason for Return

If more than 10 lenses are being returned please attach a list of, or photocopies of all serial numbers being returned.

**SHIP COMPLETED FORM AND LENSES TO LENSTEC CUSTOMER SERVICE AT THE ADDRESS ABOVE**

Total Returns \_\_\_\_\_

## SHIPPING DETAILS

Date Shipped	Shipped Via (CARRIER)	No. Cartons		Total Weight (in lbs)	AWB NUMBER

# CUSTOMER RETURN AUTHORIZATION FORM

**EVENT SPECIFICS: (Please check all boxes that apply to this event and make additional copies of Page 2 if needed for each device)**

<b>Serial Number:</b>				<b>Date of Surgery:</b>	
<b>Did the product have any Patient Contact?</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
<b>Was the lens itself:</b>	<input type="checkbox"/> Destroyed	<input type="checkbox"/> Discarded	<input type="checkbox"/> Lost	<input type="checkbox"/> N/A	
<b>If yes, please state:</b> _____					
<b>Was this an issue due to:</b>	<input type="checkbox"/> Handling/User Error? (NO product complaint)		<input type="checkbox"/> Defective Product?	<input type="checkbox"/> Other*	
<b>Specifically (check any/all that apply):</b>	<input type="checkbox"/> Loading Issues	<input type="checkbox"/> Debris on Lens	<input type="checkbox"/> Folding / Unfolding Issues		
<input type="checkbox"/> Cartridge Defective	<input type="checkbox"/> Stuck in Delivery System	<input type="checkbox"/> Broken Haptic	<input type="checkbox"/> Other (note below)	<input type="checkbox"/> Cracked / Torn Lens	
<b>Cartridge Lot #:</b> _____					
<b>Was the IOL explanted/removed from the eye?</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
<b>If yes, Date of implant</b>	_____		<b>Date of Explant</b>	_____	
<b>Was the incision enlarged to remove IOL?</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
<b>Was there any patient injury? (if yes, please explain)</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No			

**Was another lens used?** \_\_\_\_\_ **\*If yes, same model?** \_\_\_\_\_

**\*Notes / Other:**


**LENSTEC STAFF USE ONLY**

**Awareness Date:** \_\_\_\_\_

**Return Authorization Number Assigned:** \_\_\_\_\_ **By/Date:** \_\_\_\_\_




**LENSTEC, INC.**  
 1765 Commerce Avenue North, St Petersburg, Florida 33716  
 Phone: 866.536.7832 Fax: 866.536.3040

## CUSTOMER INVENTORY RETURN FORM

PLEASE USE THIS FORM FOR **UOPENED DEVICES ONLY** (OVERSTOCK, EXPIRED, CONSIGNMENT RETURNS) OPENED DEVICES SHOULD BE REPORTED ON RETURN AUTHORIZATION FORM

Customer #  Date:

**CUSTOMER DETAILS**

Company Name:		Contact Person
Address		
Telephone No.	Fax No.	Email:

**RETURN COMPLETED FORM AND LENSES LENSTEC ADDRESS ABOVE**

**ITEM DETAILS**

Device Serial No.	Model & Diopter	Replace Expired Lens? (Y/N)	Reason for Return

If more than 10 lenses are being returned please attach a list of, or photocopies of all serial numbers being returned.

Total Lenses

**FOR INTERNAL USE ONLY**

FORM PROCESSED BY & DATE

Please return lenses and completed Inventory Return form to Lenstec Returns, 1765 Commerce Avenue North, St Petersburg, Florida 33716

## LENSTEC Inventory Control

Periodically, an inventory assessment will be conducted on your consigned lenses with LENSTEC

- ✓ A report will be faxed or e-mailed from our office to the person in your office in charge of completing the inventory assessment.
- ✓ The report will list all IOLs on consignment at your facility by model, diopter, and serial number.
- ✓ The report must be checked by comparing the serial numbers listed to the IOLs on your shelf.
- ✓ After the report is completed, fax or e-mail it back to LENSTEC for verification. The toll free fax number is -1-866-536-3040 and the e-mail is [orders@Lenstec.com](mailto:orders@Lenstec.com).
- ✓ Any discrepancies or missing lenses will be verified with the person who completed the inventory assessment.
- ✓ After researching the discrepancies, a purchase order will be requested for all implanted or unaccounted for lenses.

You may request to have an inventory assessment done at any time. Please contact Lenstec's Customer Service Department toll free at 1-866-LENSTEC (536-7832) or send an email to [orders@Lenstec.com](mailto:orders@Lenstec.com).

## LENSTEC Accounting Information

- ✓ Our terms are Within 30 Days from Date of Invoice.
- ✓ We accept VISA, MasterCard, Discover and American Express.
- ✓ Our billing address is:   Lenstec, Inc.  
                                  1765 Commerce Ave N  
                                  St. Petersburg, FL 33716  
                                  Phone: 727-571-2272
- ✓ If you have any accounting questions, please contact:

Customer Service at toll free 1-866-LENSTEC (536-7832)  
or send an e-mail to – [orders@lenstec.com](mailto:orders@lenstec.com).



## LENSTEC CUSTOMER NEW ACCOUNT/UPDATE FORM

<b>Facility Name:</b>	
<b>Account Number (Assigned by Lenstec):</b>	
<b>Lenstec Sales Representative:</b>	
<b>Shipping Address:</b>	
<b>Attention:</b>	
<b>Street:</b>	
<b>City, State, Zip</b>	
<b>Billing Address:</b>	
<b>Attention:</b>	
<b>Street:</b>	
<b>City, State, Zip</b>	
<b>Facility Telephone:</b>	
<b>Facility Fax:</b>	
<b>Purchasing Contact Name:</b>	
<b>Title</b>	
<b>Phone:</b>	
<b>Fax:</b>	
<b>Email</b>	
<b>OR/Surgery Contact Name:</b>	
<b>Title</b>	
<b>Phone:</b>	
<b>Fax:</b>	
<b>Email</b>	
<b>Accounts Payable Contact Name:</b>	
<b>Title</b>	
<b>Phone:</b>	
<b>Fax:</b>	
<b>Email</b>	
<b>Physicians:</b>	
<b>Name:</b>	
<b>Name:</b>	
<b>Name:</b>	
<b>Network Affiliation (CIRCLE ONE)</b>	HCA   SCA   NOVAMED   OTHER                      NONE
<b>Bill Freight Charges to FEDEX/UPS Acct?</b>	FEDEX/UPS (Circle One) Acct#
<b>Invoice/Statement Delivery (Circle One)</b>	U.S. Mail   Email   Email Address:



## LENSTEC INTRAOCULAR LENS PRICE AGREEMENT

This Agreement is to set the price of the below intraocular lenses between Lenstec and \_\_\_\_\_ located at \_\_\_\_\_. The effective date of this agreement is \_\_\_\_\_, and is good for \_\_\_\_\_ year(s) from the date of this agreement. However, the price of any IOL model may be changed at any time with mutual agreement of customer and Lenstec Territory Representative upon signing of a new Lenstec Intraocular Lens Pricing Agreement and on file with Lenstec Customer Service.

**Lenstec Account Number:** \_\_\_\_\_

**Lenstec Territory Representative (TR):** \_\_\_\_\_

**Type of Account (check one):**  
\_\_\_\_\_ **Direct Purchase**  
\_\_\_\_\_ **Lens Consignment**

**Agreement Type:**  
\_\_\_\_\_ **New Price Agreement**  
\_\_\_\_\_ **Modify Previous Price Agreement**

**Intraocular Lens Price:**

<b>Softec HD:</b>	_____ /unit
<b>Softec HDO:</b>	_____ /unit
<b>Softec I:</b>	_____ /unit
<b>ClearView 3</b>	_____ /unit
<b>Softec HDM</b>	_____ /unit

This agreement does not constitute a contractual obligation to purchase a specified quantity of lenses and is for price guarantee only. This agreement supersedes any previously signed Price Agreement and/or Section Five and 11 of the Implant Consignment Agreement (for accounts which have lenses on consignment), and shall remain on file at Lenstec and be accompanied with an Exhibit A price detail.

Signed this \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_

\_\_\_\_\_  
Lenstec Territory Representative Signature

\_\_\_\_\_  
Customer Signature

\_\_\_\_\_  
Customer Print Name/Title

\_\_\_\_\_  
Lenstec CS Received by/Date

\_\_\_\_\_  
Facility Name

# LENS LOADING INSTRUCTIONS: USER TRAINING

**Lenstec, Inc.-** Provide lens loading training to Sales Associates and document training. This can be completed on an individual or group basis. See final page for required signatory.

## INJECTION SYSTEM COMPONENTS



Figure A: Injector I 9011S



Figure B: Injector I 9012



Figure C: Injector I 9012 FS

Figure 1



LC/CART Cartridge

Figure 2



Silicone cushion in holder

Figure 3



Lens Loader

# LENS LOADING INSTRUCTIONS: USER TRAINING

## 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 to 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) onto 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.*

Figure 1



1. **For CART series cartridges;**
  - a. Open the CART cartridge flaps and rinse each side of the chamber with saline. (See Fig 1).
2. **For LC series cartridges:**
  - a. 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).

Figure 2

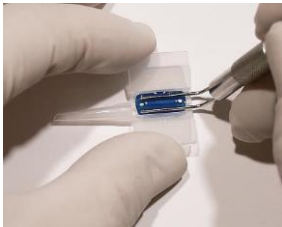


## LENS LOADING INSTRUCTIONS: USER TRAINING

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.

Figure 3



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

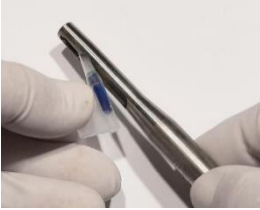
Figure 4



## LENS LOADING INSTRUCTIONS: USER TRAINING

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)

Figure 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)

Figure 6



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

Figure 7



# LENS LOADING INSTRUCTIONS: USER TRAINING

## INJECTOR AND CARTRIDGE COMPATABILITY CHART

**Note:** Using these devices outside of the compatibility chart is not recommended. All validation work and regulatory approvals were verified to be as described in the compatibility below.

### A. Cartridge Compatibility

LC Cartridge Chart				
Cartridge with silicone cushion	IOL	Injector	Tip Diameter (mm)	Lenstec IOL Power range (D)
LC 16	Softec HD	I-9011S	1.6	5.0 – 26.0
	Softec I			
	Softec HDM			Softec HDM 5.0 – 36.0
	Softec I			
LC 24	Softec HD	I-9011S	2.4	5.0 – 36.0
	Softec I / Softec HDO			
CART Series Cartridge Chart				
Cart 45S/ LC1645SI	Softec HD	I-9011S	1.6	5.0 – 26.0
	Softec I	I-9012		
	Softec HDO	I-9012 FS		
Cart M	SOFTEC HDM	I-9011S I-9012 I-9012 FS	1.7	5.0 – 36.0

# LENS LOADING INSTRUCTIONS: USER TRAINING

## 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 into 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 only with the intraocular lenses which it is validated for.
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.

### **Training Verification Documentation: Individual**

My signature on this document serves as documentation of illustrated training delivered to Lenstec Sale Representatives (RMRs, individual sales associates, etc) for the purpose of providing training knowledge to Lenstec Inc customers to ensure a safe and effective delivery of the IOL into the human eye.

\_\_\_\_\_  
Lenstec Inc Personnel

\_\_\_\_\_  
Date of training

\_\_\_\_\_  
Sales Representative

\_\_\_\_\_  
Date of training



## LENS LOADING INSTRUCTIONS: USER TRAINING

**Training Verification Documentation: Group – FOR LENSTEC USE ONLY**

My signature on this document serves as documentation of illustrated training delivered to Lenstec Sale Representatives (RMRs, individual sales associates, etc) for the purpose of providing training knowledge to Lenstec Inc. customers to ensure a safe and effective delivery of the IOL into the human eye.

<i><b>Date of training</b></i>	<i><b>Sales Associate-Trainee Name (Print first and last) i.e. sales rep, customer)</b></i>	<i><b>Sales Associate-Trainee Signature</b></i>	<i><b>Trainer- Lenstec, Inc Signature (verifiying training effectiveness)</b></i>	<i><b>Trainer-Date</b></i>