

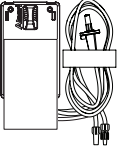
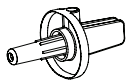



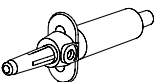
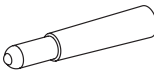


CENTURION® FMS Pack

DIRECTION FOR USE

CAUTION: The pack Directions-for-Use are not intended to substitute for the necessity of reading and understanding the CENTURION® Vision System Operator’s Manual. The Operator’s Manual, which is provided with the instrument, includes in-depth material intended to familiarize the Operating Room Staff with the controls and functions of the instrument.

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician.

DESCRIPTION: Each pack contains the sterile single-use supplies necessary to perform one lens removal procedure using the CENTURION® Vision System. Following is a list of pack items and a brief explanation of their use. Individual component availability is dependent on pack configuration.

 <p>Fluidic Management System (FMS)</p>	 <p>Active FMS Spike</p>	 <p>Ultrasonic Tip</p>	 <p>Tip Holder/Wrench</p>	 <p>I/A Tip Wrench</p>
	 <p>Gravity FMS Spike</p>	 <p>Test Chamber</p>	 <p>Infusion Sleeve (2x)</p>	 <p>Tray Support Cover</p>

FMS PACK DIRECTIONS FOR USE:

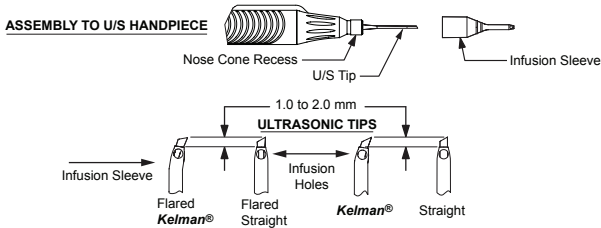
FMS Setup Procedure	
1. Open pack and aseptically transfer contents to sterile field.	Circulator
2. Drape the Tray Support Cover over both the tray and support arm of the instrument. Extend the wire loop(s) from the tray and push drape down to form pouch.	Scrub Nurse
3. For Active Fluidics procedures, install approved Alcon irrigation bag and close the Active Fluidics compartment door. Use of irrigation bags other than those approved by Alcon for use in the Active Fluidics system can result in a patient injury or system damage per section D in PRECAUTIONS and WARNINGS.	Circulator
4. Install FMS by inserting the bottom of the FMS into the instrument fluidics module. Using the handle, push FMS into the module. Ensure that the tubing and drain bag hang freely. Place the tubing sets on the draped tray. Note: Do not spike the irrigation bottle or bag prior to FMS insertion.	Circulator or Scrub Nurse
5. Connect female luer fitting (Blue) on the aspiration line to the male luer fitting (Gray) on the irrigation line.	Scrub Nurse
6. Active and Gravity FMS spikes are different as shown above. For Active FMS, spike the irrigation bag secured within the Active Fluidics compartment. Ensure that the compartment door is fully closed. For Gravity FMS, spike the irrigation bottle or bag and attach to hanger on IV pole. Squeeze drip chamber to fill approximately 2/3 to 3/4 full.	Circulator or Scrub Circulator
7. Ensure correct Doctor and Procedure setting are selected. Press Prime FMS on the Setup screen to initiate priming/test sequence. After successful completion of the priming/test sequence, the prime status indicator will change from NOT PRIMED (red) to PRIMED (Green). If the priming/test sequence fails, an advisory message will be displayed. When prime is complete, Setup will automatically switch to Fill step but will not activate until the Fill button is pressed.	Circulator or Scrub Nurse

Ultrasound Handpiece Setup

8. Thread U/S Tip onto U/S handpiece. Tighten firmly, using the Tip Holder/Wrench. Remove Tip Holder/Wrench and retain for future tip removal. **Match the proper color coding for the Ultrasonic Tip and the corresponding Infusion Sleeve per section D in PRECAUTIONS AND WARNINGS.**

Scrub Nurse

9. Thread Infusion Sleeve onto the handpiece, over the U/S Tip. Sleeve end should clear level on U/S Tip by 1-2 mm. Avoid twisting of the Sleeve. **NOTE:** Infusion Sleeves fit over both U/S and I/A tips. Orient port holes as shown:



Scrub Nurse

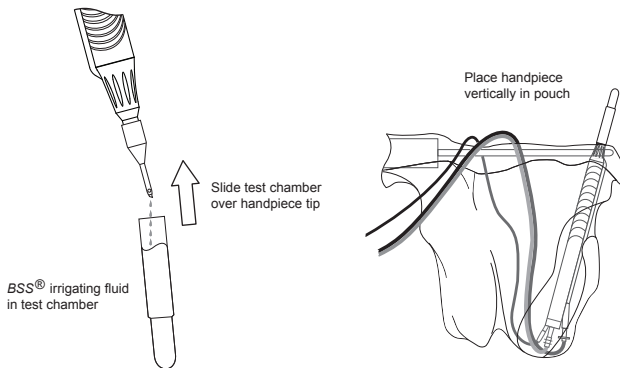
10. Connect male irrigation line luer fitting (Gray) and female aspiration line luer fitting (Blue) to U/S handpieces equipped with a locking irrigation port, turn the white luer lock clockwise to tighten and lock fitting to handpiece.

Scrub Nurse

11. Prepare handpiece for tuning and flow check. To allow irrigation fluid to flow from U/S tip, press Fill button on front panel or use the remote control to scroll to Fill and press Enter. Fill Test Chamber. Observe the stream of irrigating fluid from the irrigation and aspiration ports when the Fill button is depressed. If the stream of fluid is weak or absent, good fluidics response will be jeopardized. Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye.

Scrub Nurse
or Surgeon

12. Slide Test Chamber over Infusion Sleeve making sure that no air bubbles are present. Place handpiece vertically in the pouch created by the Tray Support Cover with Test Chamber pointing upwards.



Scrub Nurse

13. To conduct handpiece tuning and flow check, press Test Handpiece button on front panel or use the remote control to scroll to Test Handpiece and press Enter. If the handpiece fails tuning or flow test, an advisory will be displayed. The handpiece tuning process can be aborted at any time by pressing Cancel (X).

Circulator or
Scrub Nurse

14. Verify Patient Eye Level (PEL) with respect to the sensor reference indicator on the console. Press the Surgery button from the Setup screen to transition to the Surgery screen if PEL verification function is enabled. **Note:** With PEL verification disabled, after successful prime/tune of the handpiece, the system will automatically transition to the Surgery screen.

Circulator or
Scrub Nurse

Irrigation / Aspiration Handpiece Setup	
<p>15. Thread I/A tip onto I/A handpiece if required. Tighten firmly, using the I/A Tip Wrench. Remove I/A tip wrench and retain for future tip removal. Thread Infusion Sleeve onto the handpiece, over the I/A Tip. Sleeve end should clear end of I/A Tip by 1-2 mm. Avoid twisting of the Sleeve. Orient port holes as shown below and ensure that I/A Tip aspiration hole is not obstructed.</p>	Scrub Nurse
<p>16. Connect male irrigation line luer fitting (Gray) and female aspiration line luer fitting (Blue) to I/A handpiece. For I/A handpieces equipped with a locking irrigation port, turn the white luer lock clockwise to tighten and lock fitting to handpiece.</p>	Scrub Nurse
<p>17. Utilize the Fill button in the Setup screen or the optional Fill button, if added to the Surgery screen, to allow irrigation fluid to stream from the I/A tip to prime the handpiece. See the Operator's Manual for instructions to customize the Surgery screen. If the Fill button is not added, when in Surgery screen, depress footswitch to position 1 to stream irrigation fluid from the irrigation port and activate reflux function to stream fluid from the I/A tip's aspiration port. Observe the stream of irrigating fluid from the irrigation and aspiration ports. If the stream of irrigation fluid is weak or absent, good fluidics response will be jeopardized. Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye.</p>	Scrub Nurse or Surgeon
Removal of Ultrasonic Tip Or I/A Tip From Handpiece:	
<p>18. Remove the infusion sleeve. Use the appropriate tip wrench for tip removal. Slide the tip through the opening of the wrench and engage the tip by turning the wrench slightly until the flat portions of the square nut engage the Tip Wrench. Then push Tip Holder/Wrench until it is fully seated and turn counterclockwise until tip is fully removed.</p>	Circulator or Scrub Nurse

PRECAUTIONS AND WARNINGS:

- A. Use of this product may require surgical setting adjustments. Ensure that appropriate system settings are used with the system packs. Prior to initial use, contact your Alcon Sales Representative for in service information. (Within the U.S. call 800-TO-ALCON, or 817-293-0450. Outside of the U.S., contact your local Alcon Sales Representative.)
- B. If any item in the pack is received in a defective condition, Alcon is to be notified immediately. Do not use any of the contents if the sterile package is damaged or the seal is broken in any way. In these cases, please contact:

By Phone:
 In USA (800) 757-9780
 Ask for Medical Safety
 International (817) 293-0450
 Or contact local Alcon Representative

By Mail:
 Alcon Research, Ltd
 Attention: Medical Safety (AB2-6)
 6201 South Freeway
 Fort Worth, TX 76134-2099
 USA

By E-mail:
MedicalSafetyHouston@alconlabs.com

Each pack is identified by a lot number which provides traceability and should be given to Consumer Affairs Department when discussing the pack.

- C. The pack components are intended for one lens removal procedure only.
 - **Potential risk from reuse or reprocessing include: fluid path leaks or obstruction resulting in reduced fluidics performance, reduced tip cutting performance, presence of tip burrs and foreign particle introduction into the eye.**
















- D. Improper usage or assembly could result in a potentially hazardous condition for the patient:
- Mismatch of consumable components and/or use of settings not specially adjusted for a particular combination of consumable components may create potentially hazardous fluidics imbalance.
 - Use of non-approved handpieces may create potentially hazardous fluidics imbalance.
 - Use of incisions that are smaller than recommended can lead to mechanical and/or thermal damage to the eye tissues.
 - Use of irrigation bags other than those approved by Alcon for use in the Active Irrigation can result in a patient injury or system damage.

Infusion Sleeves/Type	Sleeve Color	Recommended Incision Size	Recommended Tips
0.9 mm High Infusion Sleeve	Light Purple	3.2 mm	0.9 mm and 0.9 mm ABS® MicroTip 0.9 mm Tapered ABS® MicroTip 0.9 mm Flared ABS® MicroTip 0.9 mm MiniFlared ABS® Tip 0.9 mm ABS® Mini Tip, 0.9 mm ABS® INTREPID® Balanced Tip 0.9 mm ULTRACHOPPER® Tip Standard I/A, Silicone I/A, INTREPID® I/A Tip
0.9 mm Micro Sleeve	Dark Purple	2.75 mm	
0.9 mm Ultra Sleeve	Red	2.2 mm	0.9 mm Flared ABS® MicroTip, 0.9 mm MiniFlared ABS® Tip 0.9 mm ABS® Mini Tip, 0.9 mm ABS® INTREPID® Balanced Tip 0.9 mm ULTRACHOPPER® Tip Silicone I/A, INTREPID® I/A Tip
0.9 mm Nano Sleeve	Orange	1.8 mm	
0.7 mm Ultra Sleeves	Yellow	2.2 mm	0.7 mm ABS® Mini Tip 0.7 mm ABS® INTREPID® Balanced Tip
0.7 mm Nano Sleeves	Gray	1.8 mm	

E. The equipment used in conjunction with the ALCON® pack disposables constitutes a complete surgical system. Use of disposables other than those of Alcon may affect system performance and create potential hazards and if it is determined to have contributed to the malfunction of equipment under contract, could result in the voidance of the contract and or invoicing at prevailing hourly rates.

F. Do not exceed maximum capacity of drain bag (500 ml). Excessive pressure can result from exceeding drain bag maximum capacity and potentially result in a hazardous condition for the patient.

Definitions for symbols that may appear on product labels:

	SEE DIRECTIONS FOR USE		DO NOT USE IF PACKAGE IS DAMAGED		MANUFACTURER
	CATALOG NUMBER		SINGLE USE - DO NOT REUSE		DATE OF MANUFACTURER
	BATCH CODE		USE BY : YEAR-MONTH		CONTAINS DEHP
	DOES NOT CONTAIN LATEX OR DRY NATURAL RUBBER		One of the following sterilization symbols will apply to this package		
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY			STERILE - STERILIZED BY IRRADIATION	
				STERILE - STERILIZED BY ETHYLENE OXIDE	
	CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN				PEEL POINT



Alcon Laboratories (U.K.) Ltd.
Frimley Business Park
Frimley, Camberley
Surrey, GU16 7SR, United Kingdom



© 2012, 2013 Novartis



MADE IN USA

316-3193-001 REV. B