

ANTERIOR VITRECTOMY PROBE PACK DIRECTIONS FOR USE

The **CENTURION® ULTRAVIT®** probe is for use with the **CENTURION®** Vision System.

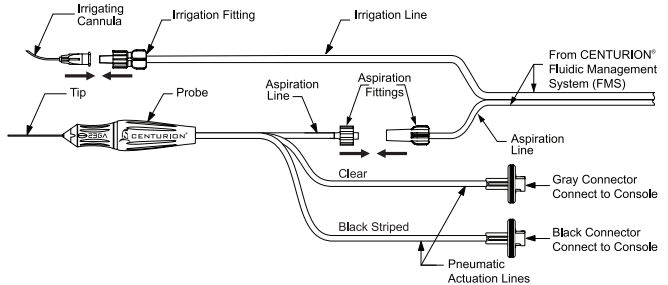
CAUTION: The Directions For Use are not intended to substitute for the necessity of reading and understanding the **CENTURION®** system Operator's Manual, which is provided with the instrument and includes in-depth material intended to familiarize the Operating Room Staff with the controls and functions of the instrument. Consult the Operators Manual for details not covered below.

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

DESCRIPTION: Each pack contains one Anterior Vitrectomy Probe and one irrigating cannula.

DIRECTIONS FOR USE:

1. After uncoiling the vitrectomy tubing set, connect the black and gray connectors to their respective pneumatic ports on console and turn clockwise until fully engaged.
2. Connect the probe aspiration fitting to the **CENTURION®** FMS aspiration fitting.
3. Using the irrigation line, fill a sterile cup with sterile BSS® irrigating solution.
4. Place the probe into the sterile BSS® irrigating solution filled cup and depress the foot pedal. The cutter should be audible upon actuation.
5. Connect the irrigating cannula to irrigation fitting. Lock irrigation fitting to irrigating cannula by sliding lock ring forward and turn clockwise to tighten.
6. Prior to entering the eye, the surgeon should verify that the cutter fully closes upon actuation. This may require lowering cut rate to achieve good visualization.
 - If the cutter is observed to not fully close or does not move when the probe is actuated, replace the probe.
 - If the cutting port is partially closed while idle, replace the probe.
 - If air bubbles are observed in the aspiration line or exiting the probe tip during priming, replace the probe.
 - If a reduction of cutting capability or vacuum is observed during the surgical procedure, stop immediately and replace the probe.
 - Do not operate the **CENTURION® ULTRAVIT®** probe in air. This could result in performance degradation and/or potential hazard.
7. For more details on priming and console set-up instructions refer to the on screen help and/or **CENTURION®** system Operator's Manual.



PRECAUTION AND WARNINGS:

1. Do not use the pack contents if the sterile package is damaged or if the seal is compromised. If any item in the package is received in a defective condition, do not use and notify Alcon immediately. Please contact:

By Phone:

In USA (800) 757-9780

Ask for Medical Safety

International: (817) 293-0450 or

Contact your 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

For traceability, each **CENTURION® ULTRAVIT®** Anterior Vitrectomy Pack is identified by a lot number. Therefore, when discussing **CENTURION® ULTRAVIT®** Anterior Vitrectomy Pack always refer to that lot number.

2. Good clinical practices dictate the testing for adequate cutting, aspiration and irrigation flow prior to entering the eye.
3. Use of this product may require surgical settings adjustments. Ensure that appropriate **CENTURION®** system settings are used with the **CENTURION® ULTRAVIT®** probe. Prior to initial use, contact your Alcon Sales Representative for in-service information. (Within the U.S. call 1-800-862-5266 or 817-293-0450. Outside of U.S., contact your local Alcon Sales Representative).
4. The equipment used in conjunction with the **CENTURION® ULTRAVIT®** Anterior Vitrectomy Pack constitutes a complete surgical system. Use of unapproved consumables or equipment may affect system performance and create potential hazards, and if it is determined to have contributed to malfunction of equipment under contract, could result in the voidance of the contract and/or invoicing at prevailing hourly rates.
5. The **CENTURION® ULTRAVIT®** Anterior Vitrectomy Pack is intended for one procedure only. Improper usage or attachment could result in a potentially hazardous condition for the patient. Alcon assumes no responsibility for complications that may arise as a result of the reuse or improper usage of an **CENTURION® ULTRAVIT®** Anterior Vitrectomy Pack.

Definitions for symbols that may appear on product label:

	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				



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