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 footpedal. 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:   By Mail:
   In USA (800) 757-9780       Alcon Research, Ltd.
   Ask for Medical Safety       Attention: Medical Safety (AB2-6)
   International: (817) 293-0450 or 6201 South Freeway
   Contact your local Alcon Representative Fort Worth, TX 76134-2099
   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**
- **AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY**
- **CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN**

![Sterilization Symbols](https://example.com/stereilization-symbols.png)

Alcon Laboratories (U.K.) Ltd.
Boundary Way, Hemel Hempstead
Hertfordshire, HP2 7UD United Kingdom

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Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099 USA
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