

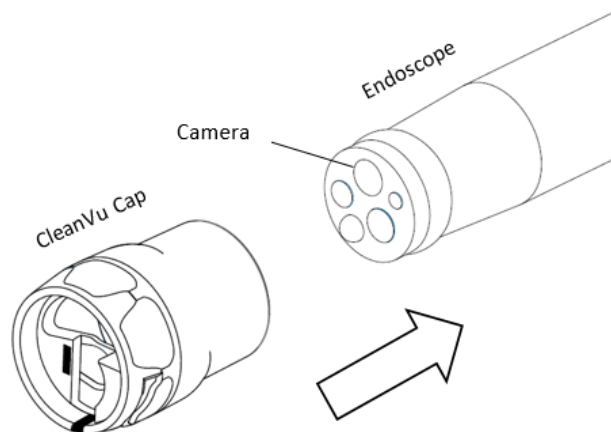
REF


ACC-CAP01

cleanVu

Single Use Distal Attachment

Instructions for Use



 CSA Medical, Inc.
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Description

The CSA Medical (CSA) cleanVu cap is a single-use distal attachment for endoscopes.














The cleanVu Box (ACC-CAP01) consists of one box of 5 pouches, each pouch containing one 14.5mm diameter cleanVu cap.

Intended Use

cleanVu is intended to be attached to the distal end of the endoscope to maintain visualization throughout a procedure.

Warnings

Category	Warning
General	<ul style="list-style-type: none">• For single use only.• Do not reuse, reprocess or resterilize.• Contamination of the device may lead to injury, illness or death of the patient.• Expired product should not be used.• Use this instrument only in combination with products recommended. If combined with products not recommended, patient or operator injury, malfunction, or equipment damage may result.• Avoid direct contact with electrocautery tools.

Symbol	Meaning
	Caution
	Consult Instructions for Use
	Manufacturer
	Date of Manufacture
	Keep Dry
	Use By Date
	Latex Free
Rx ONLY	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Single Use. Use only once. Do not reuse.
REF	Catalog Number
LOT	Lot Number/Batch Code
	Sufficient For Number of Procedures
	Do Not Use if package is Damaged
	Do Not Resterilize
STERILE EO	Sterilized Using Ethylene Oxide
	Temperature Limitation. Maximum 30°C, Minimum 15°C
	Keep Away From Sunlight

Storage

Store within conditions indicated on product label.

Specifications

cleanVu – Model O

Device compatibility was tested for the following Olympus® endoscope models:

- GIF-HQ190
- GIF-H180

The following insufflation devices are approved for use with cleanVu:

- Olympus® CO2 Regulation Unit (UCR)
- Mediators Endo Stratus™ CO2 Insufflator
 - Note: Mediator Insufflator can only be used on the 1.4 Liters per minute setting

Directions for Use

1. Remove water bottle from the scope tower.
2. Empty the water and reattach the water bottle to the scope tower.
3. Connect endoscope to CO2 insufflator and turn the insufflator on.
4. Hold finger over the endoscope's air button to redirect the flow of CO2 over the endoscope lens (Figure 1).
5. Depress finger over the endoscope's air/water button until the endoscope is clear of residual water and to drain any residual water from the umbilical insertion tube.

Figure 1. Diagram of finger placement over endoscope air button (for Model O)

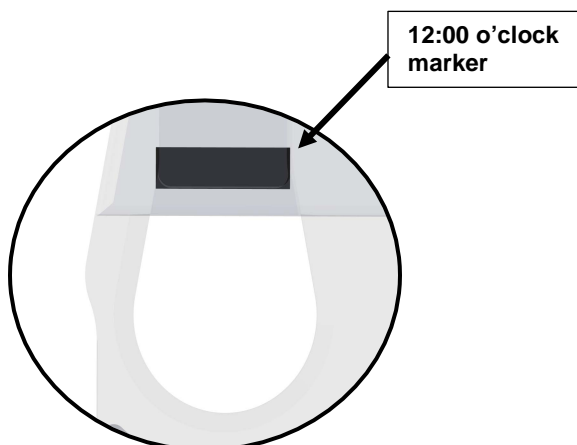


6. Remove the cleanVu cap from the pouch and confirm there are no scratches, cracks, chips or deformities.
7. Use water or saline to wet the blue portion of the cleanVu cap to facilitate installation onto the endoscope.
8. Insert the cleanVu cap onto the distal end of the endoscope

NOTE: Do not fully seat the cleanVu cap until the 12:00 o'clock reference marker has been properly aligned in the next step.

9. Refer to the endoscopic image and adjust alignment so that the internal marker is visible at 12:00 o'clock (Figure 2).

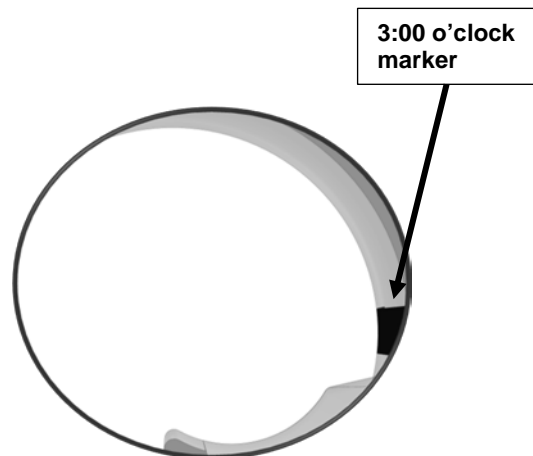
Figure 2. Diagram of the cleanVu cap placement over endoscope with the 12:00 o'clock marker in view



NOTE: If 12:00 o'clock marker is not visible, move to a white background surface.

10. Fully advance the cap onto the endoscope until the alignment marker at 12:00 o'clock disappears.
11. Continue to correctly align the cleanVu cap so that the newly visible marker is rotated to the 3:00 o'clock position and visible on the endoscopic image before use (Figure 3).

Figure 3. Diagram of the cleanVu cap alignment over endoscope with the 3:00 o'clock marker in view.



NOTE: Verify that the cleanVu cap is securely attached to the endoscope before use.

NOTE: The endoscope air button must be covered during the entire procedure to redirect the flow of CO2 over the endoscope lens.

CAUTION: If lubrication is utilized, make sure it is confined to the blue portion of the cap.

CAUTION: Do not press the cap against body cavity tissue with excessive force. This could cause patient injury, such as mucous membrane damage.

NOTE: Use a grasping forceps to retrieve the cap if it falls off the endoscope.

12. Introduce the endoscope into the patient and complete the diagnosis and/or treatment.
13. After completing the procedure, remove the cleanVu cap slowly from the endoscope and dispose of the cap per the facility's procedures.