



RE: Lopez® Enteral Valve

To Whom It May Concern:

This letter is in response to your request for information concerning the **Lopez Enteral Valve, Catalog No. M9000**. The Lopez Valve® is a three way stop cock intended to be used in conjunction with gastric or feeding tubes and designed to prevent accidental exposure of the healthcare worker to the patient's gastric fluids or mucus membrane secretions.

Performance Specifications:

Test	Product Performance Requirement
Fluid Flow	$\geq 120 \text{ ml/min @ } 36'' \text{ head height }^1$
Luer Compatibility (incoming port "A")	With male luer slips from incoming feeding sets, suction tubes, universal adapter provided
Luer Compatibility (outflow port "B")	Outgoing, tube to the patient
Luer Compatibility (syringe port "C")	60cc syringe male luer slips at the syringe port
Internal Pressure	Maintain $\geq 3 \text{ psi }^2$
Luer, device internal diameter	0.1142" which is equivalent to 8.78 fr

Materials: The Lopez Valve is constructed out of four (4) components:

- A polycarbonate valve body;
- A low linear density polyethylene valve core;
- A polyethylene cap; and
- A vinyl adapter tube.

Latex is not a component used in the manufacture of the Lopez Valve nor is Latex a component of the packaging.

Duration of Use: The device is intended to be a disposable, single use product. The Lopez Valve should be handled in a similar nature as other single use enteral products. The most common change protocol for the valve in an acute care setting is weekly. In an alternate care setting, the valve may be used longer. We recommend that each facility establish and validate their own replacement policies based on their specific applications. We further recommend that as part of the protocol, the user inspect the device prior to each use for signs of wear. If there is visible wear (black lettering worn off, leakage, cracks, etc.) the valve should be replaced. The valve may be cleaned using a mild detergent and water when appropriate.

Sterility: The Lopez Valve, Catalog M9000, is a non-sterile product. The Pediatric Lopez Valve, Catalog M9000-P is a non-sterile product. The M9000T, with tethered cap is a sterile product. The M9000PT Pediatric with tethered cap is a sterile product. The Lopez Valve can also be custom ordered as a sterile product, Catalog M9000-S.

Manufacturer: The Lopez Valve is manufactured by ICU Medical, Inc. of San Clemente, CA, USA. If you have any further questions or concerns, please contact me at (800) 824-7890 ext. 4388.

Sincerely,
Technical Support Services

¹ Feeding solution (Ensure) flows at approximately 120 ml/min at 36" head height using Ross ambulatory enteral feeding set (P/N FAN 488) attached to the Lopez Valve.

² Pressure based on average head height, above bed site, for this application (36" = 1.2 psi x 2.5 safety factor).