

Intended Use

The ViSiMax™ Laparoscopic Smoke Evacuation System is intended for the removal of surgical smoke created during minimally invasive surgery.



Description

The ViSiMax™ Laparoscopic Smoke Evacuation System is a sterile, single patient use device. The device utilizes an available suction source to withdraw surgical smoke from the peritoneal space while preventing the release of this smoke into the operating room. The device consists of an adjustable flow control valve that connects to two laparoscopic ports at the patient site and a suction source and includes two (2) color coded male luer lock connectors and one (1) standard suction connector.

Safety Information

This product is intended for use by or on the order of a physician. It is to be exclusively used by individuals who are properly trained.

The device should only be connected to trocars / gel ports used in minimally invasive surgery and a suction source.

This is a single-use device. After patient use, the device should be disposed of in accordance with hospital policy.

To shut off the device, close both valves on the laparoscopic ports to which the device is attached. Doing so will completely inactivate ViSiMax™. To resume normal function, reopen both valves and readjust the ViSiMax™ unit to the desired smoke evacuation rate.

Warnings and Precautions

Rx Only Federal law restricts this device to sale by or on the order of a physician or licensed practitioner. Use of this device should only be performed by persons having adequate training and familiarity with minimally invasive surgical techniques, and with the use of this device. Consult medical literature relative to techniques, complications, and hazards prior to use of this device.

STERILE This device is provided sterile by irradiation.



Do not use if package is open or damaged.

Do not use if package is expired, sterility may be compromised.



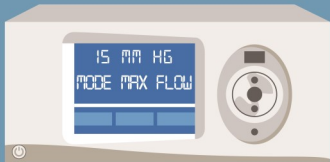
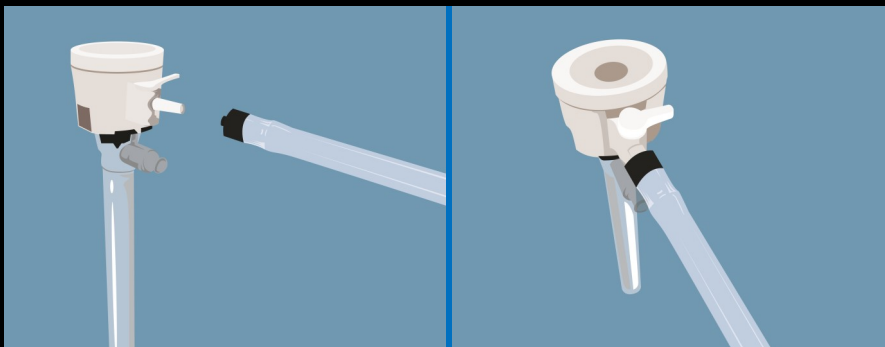

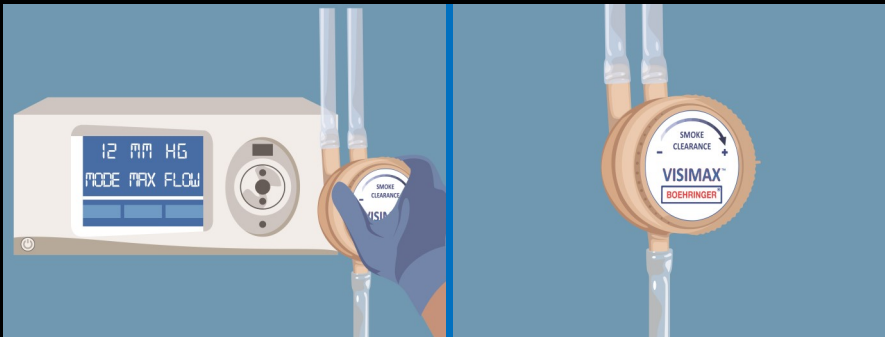
Single patient use. Do not reuse, reprocess or autoclave ViSiMax™, as this action may compromise the safety, function, and integrity of the device.

Dispose of ViSiMax™ per your facility's biohazardous waste disposal protocol.



This product is not made with natural rubber latex.

Installation Instructions

		
<p>Step 1: Insufflate</p>	<p>Step 2: Connect ViSiMax™</p>	
<p>a) Insufflate the patient cavity following standard protocol.</p> <p>b) Set insufflator flow rate to the maximum setting.</p>	<p>a) Connect each of the shorter tubes to a closed patient port using the black and blue luer lock connectors. Connect the blue suction connector to a suction / vacuum source.</p> <p>b) The blue luer indicates where smoke will be withdrawn.</p> <p>NOTE: Connecting the blue luer to the camera port is not recommended as it may result in camera fogging.</p>	
		
<p>Step 3: Activate Suction</p>	<p>Step 4: Set ViSiMax™</p>	
<p>a) Turn on the suction source.</p> <p>b) Set suction source to 'Line' or, if not applicable, as high as it will allow.</p> <p>NOTE: A minimum suction setting of 300 mm Hg is required for proper device performance.</p>	<p>a) Open both patient port valves connected to ViSiMax™. Set ViSiMax™ by turning the dial clockwise until the desired smoke removal rate is achieved as indicated by the flow rate displayed on the insufflator.</p> <p>b) For optimal performance, the smoke evacuation rate should be set to the highest rate possible that maintains an adequate operating space.</p> <p>c) Further clockwise turns of the dial will increase the smoke evacuation rate while counterclockwise turns will decrease the smoke evacuation rate.</p>	

Additional Information

Supplied: Sterile

Length: Trocar Tubing: 30"; Wall Tubing: 10'

Connection Type: Trocar Tubing: male luer lock;
Wall Tubing: standard female suction connector

Weight: 200 grams

Packaging: Box of 4, individually pouched

Shelf Life: 2 years

REF: Model 5700

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	Found on packaging labels. Definition: Reorder number.
	Found on packaging labels. Definition: Lot number.
	Found on packaging labels. Definition: Use-by-date.