

WARNINGS

This product is not intended for purposes other than standard usage to convey vacuum on the Hansatome®, Amadeus® I & II, and ACS microkeratomes.

The ML8001VS is a single-use product. Do not re-use. Re-use can result in failed suction and contamination of the surgical field.

Verify the form and function of the suction ring and connecting components before use. If the suction ring becomes deformed, it may not attach properly to the patient's eye. If the suction ring or connecting components become dysfunctional, the microkeratome system may not be able to hold vacuum constant.

Verify the integrity of the tubing set before use. If the tubing set is damaged or defective, do not use as it may not be able to hold vacuum constant. If the tubing set is defective, please contact MED-LOGICS or an authorized representative. If the expiration date has passed, do not use.

Be sure not to overstress the tubing set, as it may cause the tubing or joints to fracture. This product is designed for single-use and is therefore not intended to be used after the tubing is stretched in any way, including while removing the tubing from device. If the tubing must be disconnected from the suction ring for any reason, discard the tubing and attach new tubing set.

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P/N: 900-0806-012

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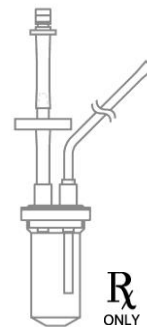


ML8001VS

Vacuum Tubing Set to fit the Hansatome®, Amadeus® I & II, and ACS microkeratomes.

The ML8001VS Vacuum Tubing Set is a sterile, disposable, single-use device for use with the Hansatome®, Amadeus® I & II, or ACS microkeratomes. It conveys vacuum pressure from the microkeratome console to the suction ring, often through a suction handle, to affix a patient's eye.

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ONLY



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Amadeus® is a product and registered trademark of SIS, AG. Hansatome® is a product and registered trademark of Bausch and Lomb, Inc. The ACS microkeratome was a product of Chiron Corp., which was acquired by Bausch and Lomb, Inc. MED-LOGICS, Inc.® is not affiliated with SIS, AG, Bausch and Lomb, Inc., or Chiron Corp.



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



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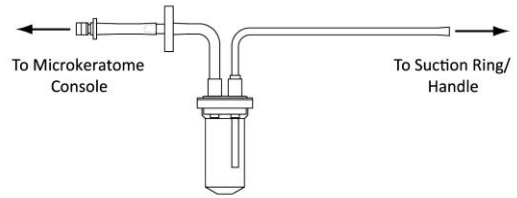
Amadeus® is a product and registered trademark of SIS, AG. Hansatome® is a product and registered trademark of Bausch and Lomb, Inc. The ACS microkeratome was a product of Chiron Corp., which was acquired by Bausch and Lomb, Inc. MED-LOGICS, Inc.® is not affiliated with SIS, AG, Bausch and Lomb, Inc., or Chiron Corp.

Symbols Used on Labeling

-  Catalog Number
-  Lot Number
-  Manufacturer
-  Authorized Representative in the EU
-  Authorized Representative in the UK
-  CE Marking and Authorized Rep No.
-  Consult Instructions for Use
-  Caution
-  Do Not Reuse
-  Do not use if package is damaged
-  Sterilized using Ethylene Oxide
-  For Use by, or on the Order of, a Physician
-  Date of Manufacture: (YYYY-MM)
-  Use by: (YYYY-MM)
-  Medical Device
-  Unique Device Identifier

Instructions for Use

1. Remove vacuum tubing set from the sterile pouch.
2. Connect vacuum tubing to microkeratome console and to suction ring handle as shown below:



Storage Conditions

The MED-LOGICS Vacuum Tubing Sets have no special storage conditions, but should be stored under normal warehouse conditions, which includes protection from moisture, extreme cold (less than 5°C), and excessive heat (greater than 40°C).

















CAUTIONS

U.S. Federal Law restricts sale and use to or on order of a Physician.

EtO sterilization (EO) is performed on the tubing pouches. Never open the tubing pouch until just before use. Do not use the tubing if its packaging is broken. The sterilization effect may be weakened, and the tubing may become nonsterile.

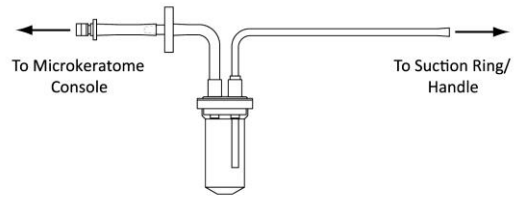
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