

WARNINGS

This product is not intended for purposes other than standard usage to convey vacuum on the MED-LOGICS ML7® and Moria® LSK One, M2, and CB microkeratomes.

The ML8060VS 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 a constant vacuum.

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

Be sure not to overstress the vacuum 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 the device. If the vacuum tubing must be disconnected from the suction ring for any reason, discard the tubing and attach a new vacuum tubing set.

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P/N: 900-0807-012

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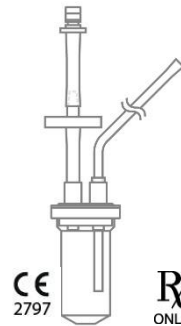
P/N: 900-0807-012



ML8060VS

Vacuum Tubing Set to fit the ML7®, Moria® LSK One, M2, and CB microkeratomes.

The ML8060VS Vacuum Tubing Set is a sterile, disposable, single-use device for use with the e MED-LOGICS, Inc.®, ML7 and Moria® LSK ONE, CB, AND M2 Microkeratomes. It conveys vacuum from the microkeratome console to the suction ring, often through a suction handle, to affix a patient's eye.



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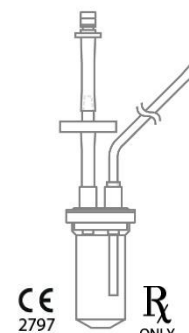
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












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Symbols Used on Labeling

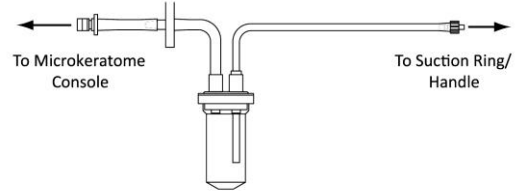
	Catalog Number
	Lot Number
	Manufacturer
	Authorized Representative in the EU
	Authorized Representative in the UK
	CE Marking and Authorized Rep No.
	Consult Instructions for Use
	Caution
	Do Not Reuse
	Do not use if package is damaged
	Sterilized using Ethylene Oxide
	For Use by, or on the Order of,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

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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

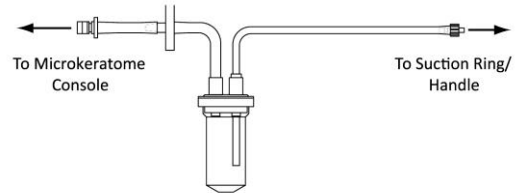
U.S. Federal Law restricts sale and use to or on order of a Physician.

EtO sterilization 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.

This product is intended for use by experienced physicians or technicians who have received proper instruction on the use of the microkeratome system being used.

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