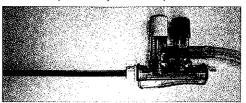


PRODUCT INFORMATION DATA SHEET

Please read the following information thoroughly before using this device. Product Ref:

LM201, LM202, LM2025, LM20210



Description:

LocaMed Suction Irrigation set is a sterile, single use and multifunctional instrument which achieves two functions, suction and irrigation in a single orifice. LocaMed Suction Irrigation set consists of a suction irrigation tubing, probes for pool suction and irrigation. The suction with removable monopolar spatula, L Hook and electrode probe is also available.

Intended use:

LocaMed Suction Irrigation set is available with an array of probe designs to facilitate lavage during laparoscopic surgery. This device has application in laparoscopic gynecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopic to aid visualisation.

Contraindications:

This device is not intended for use when endoscopic techniques are contraindicated.

Recommended Use:

The Suction & Irrigation Set is intended for use during operative laparoscopy.

Preparation:

- 1. Whilst adopting an aseptic technique, remove the sleeve containing the Suction & Irrigation set from the sterile packaging.
- 2. Close the white clamp on the tubing. Remove the safety cap from the spike and insert the spike into the irrigation nump.
- 3. Please follow instructions provided by suction machine manufacturer for details of connection of the suction adapter to the suction bottle
- 4. The Suction/Irrigation instrument should be inserted through the trocar. Please note the Suction/Irrigation device is a 5mm instrument and an appropriate trocar diameter must be selected. However, using the LM20210 probe may change the diameter to 10mm and it is suited with a trocar that has the same diameter.
- 5. The Suction option is selected by depressing the White trumpet valve on the device. The irrigation option is selected by depressing the Blue trumpet valve. Please follow instructions provided by suction machine and irrigation pump manufacturer for further information on the safe use of their device.
- 6. Once the endoscopic procedure is completed, dispose of this device in accordance with local regulations.

Wanings and Precautions:

- Caution: Federal law restricts this device to sale by or on the order of a physician. Do not use when the package is opened or damaged.
- · This device is EO sterilized and for single use only. Please do not re-use or re-process to avoid irreversible injury such as cross-infection or injury injury caused by device malfunction.
- Store this device in a dry, clean and safe place. Keep the device away from flammable and combustible chemicals or materials.
- Prior to each use, inspect the product for: loose, bent, broken, cracked, worn, or fractured components. Do not use the product if it is damaged
- Endoscopic procedures should be performed only by physicians with adequate training and knowledge of these procedures. In addition, medical literature should be consulted regarding techniques, hazards, contraindications, and complications prior to the performance of these procedures.
- Before utilizing endoscopic instruments and accessories supplied from different manufacturers, verify compatibility and ensure that electrical isolation of grounding is not compromised.
- A thorough understanding of techniques and principles involved in electrosurgical procedures is necessary to avoid burn or shock hazards to patient and/or operator.
- If electrocautery is required, this instrument should be used with certified unipolar electrosurgical generators.
- Keep the HF power output as low as possible to achieve the desired end effect. Refer to instructions for use provided by the manufacturer of electrosurgical generator to ensure that all safety precautions are followed.
- Using a metal trocar sheath in conjunction with a plastic site stability device creates a potential hazard when using electrosurgical instruments.
- Certain applications of the HF device can cause sparks. Follow the safety instructions in the HF device's instructions for use very carefully.
- Prior to switching on the HF device, make sure that the product's working tip is not touching any accessory or fluid that conducts electricity. Keep the working tip in the user's visual field when ever HF power is activated.
- Do not put down the instrument on the patient or in the immediate vicinity of the patient.



EC REP

Unit 4 The Enterprise Centre, Coxbridge Business Park, Alton Road - Farnham, Surrey - GU10 5EH, United Kingdom

Tel: +44(0)1252413051 Fax: +44(0)1252727916 www.locamed.com

MedNet EC-REP GmbH

Borkstrasse 10, 48163 Münster, Germany









