

INSTRUCTIONS FOR USE

ENGLISH



THE FRANKENMAN MAXIMA™ SINGLE USE SUCTION AND IRRIGATION SYSTEM

Please read these instructions carefully before using the FRANKENMAN MAXIMA™ single use suction and irrigation system.

There may be serious consequences if the following recommendations are not complied with.

All surgical procedures using the FRANKENMAN MAXIMA™ single use suction and irrigation system must be carried out solely by doctors who have been specifically trained and have sufficient experience to use laparoscopic and surgical technique.

Any surgeon who undertakes a procedure must be aware of the risks and possible complications involved with this surgical technique. Ensure that the patient has been informed about the way the operation will take place, as required by local recommendations.

These instructions are not a reference document for surgical techniques; please refer to existing works for all information concerning surgical operations and techniques utilising suction and irrigation devices and the complications and risks that may be involved.

IMPORTANT NOTE

These instructions contain solely information concerning the FRANKENMAN MAXIMA™ suction and irrigation system with and how to use it. It must in no way be considered to represent general instructions concerning the techniques for using suction and irrigation system from other manufactures.

FIELD FOR USE OF THE FRANKENMAN MAXIMA™ SUCTION AND IRRIGATION SYSTEM

The FRANKENMAN MAXIMA™ suction and irrigation system is a single-use medical device designed for cleansing of the abdominal and other cavities and internal organs during open and laparoscopic surgical techniques and aspiration of debris.

CONTRA- INDICATIONS

The FRANKENMAN MAXIMA™ suction and irrigation system is counter indicated when there is a contra indication for endoscopic surgery.

DESCRIPTION OF THE INSTRUMENT

The FRANKENMAN MAXIMA™ single use suction and irrigation system consists of 3.0 metres of double tubing, with fluid bag spike and a clamp fitted on the irrigation tube, and a universal flexible connector on the suction tube. On the other side, the cannula (diameter 3 mm, 5 mm or 10 mm, length 280 mm, 320 mm and 420mm) is connected to the tubing by the double piston hand-piece.

The irrigation circuit corresponds to the blue piston, and its tubing is fitted with a clamp and the pouch spike.

The aspiration circuit corresponds to the red piston, and its tubing is fitted with the universal flexible connector.

SPECIFICATIONS

FRANKENMAN MAXIMA™ single use suction and irrigation system

DESCRIPTION	SIZE	PRODUCT CODE	QTY/BOX
MAXIMA™ Suction and Irrigation set complete with tubing and connectors with 280 mm cannula tube.	3MM	SIS328	10
	5MM	SIS528	10
	10MM	SIS1028	10
MAXIMA™ Suction and Irrigation set complete with tubing and connectors with 320 mm cannula tube.	3MM	SIS332	10
	5MM	SIS532	10
	10MM	SIS1032	10
MAXIMA™ Suction and Irrigation set complete with tubing and connectors with 420 mm cannula tube.	3MM	SIS342	10
	5MM	SIS542	10
	10MM	SIS1042	10
MAXIMA™ Suction and Irrigation 280 mm Cannula tube only	3MM	SIS328T	10
	5MM	SIS528T	10
	10MM	SIS1028T	10
MAXIMA™ Suction and Irrigation 320 mm Cannula tube only	3MM	SIS332T	10
	5MM	SIS532T	10
	10MM	SIS1032T	10
MAXIMA™ Suction and Irrigation 420 mm Cannula tube only	3MM	SIS342T	10
	5MM	SIS542T	10
	10MM	SIS1042T	10

The device is delivered in sterile packaging. The FRANKENMAN MAXIMA™ Suction and Irrigation device is designed for single use.

Once the sterile packaging has been opened, and whether or not it has been used, the suction and irrigation system must not be re-sterilised.

USING THE FRANKENMAN MAXIMA™ SUCTION AND IRRIGATION SYSTEM

Before using the FRANKENMAN MAXIMA™ suction and irrigation system, the operating field must be prepared according to the usual techniques.

Prior to using the suction and irrigation system, check that the diameter of its suction cannula is suitable for the trocars being used.

INSERTION PROCEDURE

1. Open the sterile packaging according to correct practice for operating fields.

2. Ensure the irrigation cannula, hand-piece and about one metre of tubing remain on the drape.

Note: The FRANKENMAN MAXIMA™ Suction and Irrigation system can be configured to operate in either a pistol grip or palm grip. The product is supplied in Pistol Grip set up. To adjust this the fitted suction cannula can be detached by rotating fixing ring counter clockwise and re-attached in the palm position, on the lower handle, by removing fitted sealing cap with counter clockwise movement and attaching suction cannula with clockwise rotation.

3. Close the clamp on the irrigation tubing, remove the protective cap from the spike and pierce the pouch or bottle of solution in sterile fashion.

Aspiration of the body liquids and/or debris resulting from cleansing is effected by suction using the operating room main vacuum system.

4. Open the irrigation tubing clamp to allow the liquid through, and expel all the air from the tubing before using the cannula. When a fluid bag change is necessary, close the irrigation tube clamp and replace the bag or bottle of solution in sterile fashion.

At the end of the operation, close the irrigation tube clamp, disconnect the universal flexible connector on the aspiration, and discard the whole cannula-handle-tubing assembly.

The sterile packaging and contents must be destroyed, under the following circumstances:

- if the packaging has been subjected to strong compression or is obviously damaged.
- if traces of humidity are visible on the cardboard package,
- if the bag has been holed.

STORAGE CONDITIONS

Storage temperature between 5°C and 35° C.

Avoid all prolonged exposure to high temperatures.

The Frankenman suction and irrigation system is sterilized by Ethylene Oxide, the shelf life is 2 years from the sterilization date.

For transport conditions, apply all the instructions above.



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