



Instruction for Use

Product

Laparotomy Pack

Intended Use

It is used for clinical abdominal surgery in medical institutions.

NO.	Name	Intended Use
1.	Sterile Field	Used to package medical devices.
2.	Instrument table cover	Used to cover non surgical areas of surgical patients to reduce the risk of surgical infections; Side skirts are used to block the body parts of surgical patients and avoid contaminating the operating table; A headrest can provide more comfortable head support for surgical patients.
3.	Laparoscopy Drape	Hygiene and nursing supplies used on hospital beds or examination beds.
4.	Drape Sheet	Used to provide a physical barrier to protect the surgical area from contamination.
5.	Utility Drape	Used to prevent microbial contamination.
6.	Reinforced surgical gown	Surgical Gown is intended to be worn by health care personnel during surgical procedures to protect both the patient and health care personnel from the transfer of microorganisms, body fluids, and particulate matter.
7.	Medical Mask	Medical mask used for clinical medical personnel wearing during invasive procedures, and providing protection for receiving treatment patients and implementation of invasive operations medical personnel to stop the blood, body fluids and spatter spreading.
8.	Hand Towels	Used for wiping hands.
9.	Disposable Examination Gloves	Used by medical staff to prevent cross infection between patients and users or to handle contaminated medical materials during the examination, diagnosis, and treatment process.
10.	Gauze Sponge without X-ray	Gauze Sponge without X-ray is used to cover/clean wounds or abrasions and absorb their exudates, absorb body-surface exudates. It is only intended to be used as a mechanical barrier; and not contact mucous membrane or manage the micro-environment of injured skin.
11.	Mayo Stand Cover	It is used to maintain the sterility of the Meiya stent

Intended Patient Population

Patients with exudate from laparotomy, which including all age groups.

Age: no restrictions

Weight: no restrictions

Gender: pregnant woman

Nationality: multiple

Intended User

Medical professionals in a specialty, clinical nurses.

Intended Using environment

This device is only designed for use in hospitals.

Contraindication

None

Potential complications

Infection;

Foreign body reaction

Medical Conditions

laparotomy

Indications

Preparation for cesarean section surgery

Accessories or Other Device Combination use

None

Model /Size

MG-LP-01, MG-LP-02

Caution

- 1) Do not re-use;
- 2) Do not use if package is damaged;
- 3) Consult instructions for use or consult electronic instructions for use.
- 4) Keep away from sunlight, Keep dry
- 5) Please inform the manufacturer and competent authority in case of any adverse events related to the device occur.
- 6) This product is sterilized with EO and has a shelf life of 3 years. Please use it within the product's shelf life.

Storage conditions

Products should be stored in a sealed, moisture-proof, ventilated and dry place.

Disposal

The product is disposable and should be disposed of according to local medical waste regulations after use.

Shelf-life

3 years

Sterilization

The product is sterilized by EO. If the package is damaged, please do not use it

Definitions of symbol used

Signs	Description	Signs	Description	Signs	Description
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Signs	Description	Signs	Description	Signs	Description
	Trademark of Manufacturer		Batch number		Date of Manufacture
	Medical device		Model number		Country of manufacturer
	Use-by date		Sterilized using ethylene oxide		Caution
	Consult instructions for use		Catalogue number		Unique Device Identifier
	Single sterile barrier system		Double sterile barrier system		Keep away from sunlight
	Do not reuse		Do not use if the package is damaged		Keep dry
	CE marking of conformity, and Notified Body Code		Authorized representative in the European Community		Manufacturer

Manufacturer



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Web: www.medigauze.com

Tel: 86+513-88240958

SRN: CN-MF-000009960

European Authorized Representative



Name: Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany

E-mail: shholding@hotmail.com

SRN: DE-AR-000000001

Incident reporting

The user and/or patient shall report any serious incident that has occurred in relation to the device to Haian Medigauze Co., Ltd., and the competent authority of the EU Member State in which the user and/or patient is established.

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