Instruction for Use

<Product: Non-Sterile Lap Sponge with X-Ray detectable Material >

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Date	Version	Revision History
2024-03-20	A/0	Initial
2024-06-14	A/1	Update according TD assessment

Instruction for Use

This device is supplied as non-sterile condition, in any condition that intended to be used in a sterile state, the end user should sterile the product before using!!! Always disposal this device after use, this is a disposable device.

The processor has the responsibility to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. Validation and routine monitoring of the process is requires, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences!!!

Device name

Non-Sterile Lap Sponge with X-Ray detectable Material

Model

MG-NLSWX

Intended purpose

Non-Sterile Lap Sponge with X-Ray detectable Material is intended to be used inside the body, on a surgical incision or applied to internal organs or structures to control bleeding, absorb fluid, or protect organs or structures from abrasion, drying, or contamination during a laparotomy procedure. It can be detected through X-ray device. This device is supplied as non-sterile condition, in any condition that intended to be used in a sterile state, the end user should sterile the product before using. This is a disposable short-term use device which, continuous use between 60 minutes and 24 hours.

Expected clinical benefits

a) Its highly absorbent assists in keeping the surgical site free of body fluids, providing surgeons with a clear field of view and clean work space.

b) X-ray detectable performance make it easily be identified, located and extracted to reduce or prevent the retained sponges, reducing complications.

Intended Patient Population

Patients who are under laparotomy procedure, which including all age groups.

Intended User

This device should only be used by professional.

Intended Using environment

This device is only designed for use in hospitals.

Contraindication

There are no noted contraindications.

Potential complications

Infection;

Foreign body reaction

Allergic to X-ray detectable sheet /X-ray detectable thread, or cotton

Medical Conditions

Laparotomy

Indications

Absorb the exudate from the operation site

Cleaning and Disinfection

Device	Non-Sterile Lap Sponge with X-Ray detectable Material
Advice	This device is supplied as non-sterile condition, in any condition that intended to be used in a sterile state, the end user should sterile the product before using!!! Always disposal this device after use, this is a disposable device.
Reprocessing Instructions	
Preparation at the Point of Use:	Check all packages if it integrity before sterilize. Always record the date and quantity of sterilization for remind. Always marke labels to distinguish between non-sterilized and sterilized
Packaging	This device is provided in an appropriate packaging material (paper-plastic bag) for sterilization already. The packaging material and system are comply to ISO 11607 series. Repackaging is no need. Note: Always count the number of gauze pieces.
Cleaning and disinfection	not applicable
Sterilization	Sterilization of products by applying a EO sterilization process (according to EN ISO 11135: 2014) under consideration of the respective country requirements. Ethylene oxide sterilizers should comply to EN 1422. Following sterilization parameters are commonly used: Ethylene Oxide Sterilization: 80% Ethylene Oxide (EO),20% Carbon dioxide （CO2 ） with a concentration of 540~550 mg/L @ 55°C and 40% relative humidity for 480 minutes, 7days aeration time at 13.5 ºC. detail refer table below

	Parameter		**Requirement**	**Tolerance**
Pretreatment in cabinet	Insulation temperature setting		55℃	±5
	Insulation relative humidity		30-80%RH	/
	Heat preservation time setting	Temperature ≥ 14.9 ℃	240min	±3
		Temperature 10 ℃ - 14.9 ℃	360min	
		Temperature 5 ℃ - 10 ℃	450min	
		Temperature 0 ℃ - 5 ℃	570min	
Vacuum pumping Leak test	Initial vacuum setting		-70kPa	±1
	Time to reach vacuum degree		≤30min	/
humidification Ethylene oxide injection	Pressure holding time setting		6min	±1
	Pressure change		≤1kPa	/
expose	Pressure rise setting		2.0kPa	±0.5
clean Vacuum pumping Leak test	Injection time		25min	±5
	Pressure rise setting		43kPa	±0.5
	Final pressure		-22kPa	±5
	Injection weight		19kg	±2
humidification Ethylene oxide injection	Sterilization temperature setting		55℃	±5
	Exposure time setting		480min	±3
expose clean	Vacuum pumping setting		-70kPa	±1
	Recompression		-15~-10kPa	/
	Setting of cleaning times		4 times	/
aeration	temperature		≥13.5℃	
	time		7 days	
After sterilization	Remove the product from the chamber. Let the product cool down at room temperature for at least 30 minutes. Inspect the sterilization package are not damaged.			
Storage	Storage of sterilized device in a dry, clean and dust free environment at room			

	temperatures, use the device before expaire date.
Transport	Use clean container for transfer device and be careful do not damage the package.
Additional Instructions	None
It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.	

Warning

1) DO NOT use device that has not been properly steriled before use. Failure to do so can result in the transmission of infectious agents and compromise patient safety.

2) DO NOT use a device if it is visibly damaged or has any foreign matter, breaks, moldy, or holes. Using this device may can cause cross-contamination and potentially lead to patient harm.

3) This product has a shelf life of 5 years. DO NOT use a device that is past its expiration date.

Caution

1) Always follow instructions for use.

2) Keep away from sunlight, Keep dry

3) Always count the number of gauze pieces.

4) Always record the date and quantity of device sterilized for remind.

5) Always make labels to distinguish between non-sterilized and sterilized

6) This is a disposable short-term use device which continuous use less than 24 hours.

7) Please inform the manufacturer and competent authority in case of any adverse events related to the device occur.

Storage conditions

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

Shelf-life

The product shelf life is 5 years.

Disposal

This device cannot be reused, and should be disposed of according to local waste disposal requirements after use

Definitions of Signs

Signs	Description	Signs	Description	Signs	Description

Signs	Description	Signs	Description	Signs	Description
	Trademark of Manufacturer	LOT	Batch number		Date of Manufacture
MD	Medical device	#	Model number	CC	Country of manufacturer
	Use-by date		Consult instructions for use		Caution
	Non-pyrogenic	REF	Catalogue number	UDI	Unique Device Identifier
CE 0123	CE marking of conformity, and Notified Body Code	NON STERILE	Indicates a medical device that has not been subjected to a sterilization process		Keep away from sunlight
	Do not reuse		Do not use if the package is damaged		Keep dry
	Indicates the entity importing the medical device into the locale	EC REP	Authorized representative in the European Community		Manufacturer

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SRN：CN-MF-000009960

EC REP 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.

Rev. A Issued date: XXXXXX (latest revision)