



Instruction for Use

Product

Gauze Ball without X-ray

Intended Use

Gauze Ball 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.

Intended Patient Population

Patients with exudate from wound, 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

With wound exudate

Indications

Patients with exudate from wound.

Accessories or Other Device Combination use

None

Model /Size

MG-GB-0505, MG-GB-0606, MG-GB-0808, MG-GB-0909, MG-GB-1010, MG-GB-1212, MG-GB-1515, MG-GB-1818, MG-GB-2020, MG-GB-2025, MG-GB-2525, MG-GB-3030, MG-GB-3035, MG-GB-3040, MG-GB-3535, MG-GB-4040, MG-GB-4545, MG-GB-5050, MG-GBC-1515, MG-GBC-1818, MG-GBC-2222

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 5 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

5 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
	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		Authorized representative in the European		Manufacturer

Signs	Description	Signs	Description	Signs	Description
	Code		Community		

Manufacturer

Name: Haian Medigauze Co., Ltd.

Add: Jiaoxie Industry Park, 226633Haian, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

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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