Instruction for Use

CE 0123

Product

Gauze Sponge with X-Ray

Intended Use

Gauze Sponge with X-Ray is intended to be used to absorb the exudate in the body during the operation and to support organs and tissues during the operation.

Intended Users

This device should only be used by professional medical staff who have been fully trained and qualified in the use of Gauze sponges with X-Ray techniques and surgeries.

Intended Patient Populations

Patients undergoing surgery, which including all age groups.

Age: no restrictions

Weight: no restrictions

Gender: no restrictions

Nationality: multiple

Intended using environment

This device is only designed for use in hospitals.

Side effect

Wound infection caused by improper operation, The quantity of gauze was not determined during the operation, resulting in gauze left in the body.

Medical Conditions

With wound exudate

Indications

Patients with exudate from wound.

Contraindications

None

Cautions

1) This product is for single use only, please do not reuse it.

2) Please check the integrity of the package before use, if the package is damaged or contaminated, please do not use it.
3) Please read the instructions carefully before use. If the product has moldy, yellow or expired, please do not use it.
4) Please place in a dry place to prevent fire and moisture.
5) Please inform the manufacturer and competent authority in case of any adverse events related to the device occur.
6) This product is for healthcare professionals only.

Use in conjunction with other medical devices

None

Model

Items	Model	L	W	Layer
1	MG-GSWX	5	5	4P,8P,12P,16P,32P
2	MG-GSWX	75	5	4P,8P,12P,16P,32P
3	MG-GSWX	10	5	4P,8P,12P,16P,32P
4	MG-GSWX	15	5	4P,8P,12P,16P,32P
5	MG-GSWX	20	5	4P,8P,12P,16P,32P
6	MG-GSWX	6	6	4P,8P,12P,16P,32P
7	MG-GSWX	75	6	4P,8P,12P,16P,32P
8	MG-GSWX	8	6	4P,8P,12P,16P,32P
9	MG-GSWX	9	7	4P,8P,12P,16P,32P
10	MG-GSWX	10	7	4P,8P,12P,16P,32P
11	MG-GSWX	75	75	4P,8P,12P,16P,32P
12	MG-GSWX	10	75	4P,8P,12P,16P,32P
13	MG-GSWX	15	75	4P,8P,12P,16P,32P
14	MG-GSWX	20	75	4P,8P,12P,16P,32P
15	MG-GSWX	8	8	4P,8P,12P,16P,32P
16	MG-GSWX	10	8	4P,8P,12P,16P,32P
17	MG-GSWX	9	9	4P,8P,12P,16P,32P

18	MG-GSWX	10	9	4P,8P,12P,16P,32P
19	MG-GSWX	15	9	4P,8P,12P,16P,32P
20	MG-GSWX	10	10	4P,8P,12P,16P,32P
21	MG-GSWX	12	51	4P,8P,12P,16P,32P
22	MG-GSWX	13	10	4P,8P,12P,16P,32P
23	MG-GSWX	15	10	4P,8P,12P,16P,32P
24	MG-GSWX	20	10	4P,8P,12P,16P,32P

Materials

No.	Part	Material
1.	Gauze sponge	Absorbent gauze: cotton
2.		Blue ribbon: cotton
3.		Sewing thread: cotton
4.	X-Ray-thread	Blue barium line/ tablet: PP+$BaSO_4$

Shelf-life

5 years

Sterilization

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

Definitions of Signs

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	STERILE EO	Sterilized using ethylene oxide		Caution
	Non-pyrogenic	REF	Catalogue number	UDI	Unique Device

Signs	Description	Signs	Description	Signs	Description
					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
	Do not resterilize		Authorized representative in the European Community		Manufacturer
	CE marking of conformity, and Notified Body Code		Consult instructions for use	/	/

Manufacturer

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