Document Name: Instruction for Use

Document No.:IFU- NWSXR-NS-M02020302Product :Non-Sterile Non Woven Swabs(with x-ray thread)Version:01



Instruction for Use

[Product Name]

Non-Sterile Non Woven Swabs(with x-ray thread)

[Product Composition]

The product is mainly composed of polyester ,viscose and x-ray thread

[Intended Use]

It's intended to be used inside the body, on a surgical incision to control bleeding and absorb fluid. X-ray detectable element helps to detect the device left inside patient. This is a professional and single use device. Normally intended for continuous use for not more than 24 hours.

[Intended User]

Medical staff

[Intended patient population]

Used for all age groups.

[Handling Instruction]

- > Clean the wound area, hands and instruments in accordance with normal procedures.
- Check the package, if the package is not intact, or the product is abnormal compared with others, it must be replaced.
- Open the packaging and take out the product, gently place the product on the wound that needs to absorb exudates.

[Warnings and Precautions]

- > The product is disposable and cannot be reused.
- Stop using if product has any defect.
- Stop using if the product has expired.

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> Non-sterile products should be sterilized by distributor or end user before using.

Recommended sterilization methods before using: ETO sterilization

Recommended Parameter:

Vacuum depth -90kpa 30-85%RH

Exposure temperature 50-60 $^\circ$ C Exposure dwell time 4~6 hours

- In order to ensure the microorganism not exceed standard, it is recommended that the maximum storage time before sterilization is 5 years.
- It is recommended that the product be packaged in the sterile barrier system before sterilization, SBS packaging should meets the requirement of ISO 11607-1.

[Shelf Life] 5years

[Contraindications]

Do not use on patients with a known hypersensitivity to the product itself or to its components.

[Side Effects]

None

【Disposal】

Disposal should be handled according to local environment procedures.

[Special Storage Conditions and Methods]

The product should be stored in a cool and dry place and avoid direct sunlight.

The transportation should prevent the weight, sun and rain.

[Notice]

Any serious adverse event related to this product must be report to Allmed Medical Products Co., Ltd or authorized representative or national health authority in your country.

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[Explanation of figures, symbols and abbreviations used in labels]

2	Do not reuse	NON STERILE	Non-sterile	\triangle	Warnings and Precautions		Manufacturer Name Address
\sum	Used-by date	CE	CE Symbol	M	Manufacture Date	I	Consult instructions for use
LOT	Batch Code	REF	Catalogue Number	EC REP	Name and Address of European Union Representative	MD	medical device
	Do not use if package is damaged	×.	Keep away from sunlight	Ť	Keep dry		importer

[Manufacturer] Allmed Medical Products Co.,Ltd

[Address] No.18 Qi xing Road, Majiadian Town, 443200 Zhijiang City, Hubei Province, CHINA

[European Representative] Shanghai International Holding Corp. GmbH(Europe)

[Address] Eiffestrasse 80, 20537 Hamburg, Germany

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