

Instruction for Use

【Product Name】

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

【Product Composition】

The product is mainly composed of polyester ,viscose ,x-ray thread, silicone ring(if applicable).

【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.

- 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℃ 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】

	Do not reuse		Non-sterile		Warnings and Precautions		Manufacturer Name Address
	Used-by date		CE Symbol		Manufacture Date		Consult instructions for use
	Batch Code		Catalogue Number		Name and Address of European Union Representative		medical device
	Do not use if package is damaged		Keep away from sunlight		Keep dry		importer

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