

Document Name:	Instruction for Use
Document No.:	IFU-GSXR-NS- M02010502-02
Product :	Non-Sterile Gauze Swabs(with x-ray thread)
Version:	02



Instruction for Use

【Product Name】

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

【Product Composition】

The product is mainly composed of white or dyed bleached gauze 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 Professional

【Intended patient population】

Used for all age groups excluding infants.

【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.

【Reprocessing Instruction】

This product is supplied non-sterile and must be sterilized before using. Sterilization must be performed before using by distributor or end user. The provided processing instructions have been validated by Allmed Medical Products Co.,Ltd.

1. Preparation at Point of Use

- Inspect all packages for intactness before sterilization.
- Record sterilization date and quantity for traceability.
- Apply labels to distinguish sterilized products from non-sterilized ones.

2. Packaging Requirements

The product is pre-packed with paper-plastic sterilization pouches complying with ISO 11607 series standards. Repackaging is not required.

3. Sterilization Method

Recommended sterilization methods before using: ETO sterilization

Preconditioning Process	Parameter items	Unit	Set point	Acceptable range	
				Min value	Max value
Preconditioning parameter	Space Temperature	°C	50	40	60
	Space Humidity	%	60	40	80
	Preconditioning time	Hrs	N/A	12	48
	product temperature after preconditioning process	°C	N/A	38	60
Product transfer	Transfer time	Mins	N/A	N/A	60
Sterilization Process	Process Parameter	Unit	Set point	Acceptance range	
				Min value	Max value
Initial Vacuum	Initial vacuum	KPa	-90	-92	-88
	Initial vacuum time	Mins	N/A	10	45
Leak test	Leak test time	Mins	10	9	12
	Delta P during leak test	KPa	N/A	N/A	2
Nitrogen displacement	Nitrogen displacement times	N/A	1	1	1
	Nitrogen Injection End Pressure	KPa	-10	-12	-8
	Nitrogen injection time	Mins	N/A	7	30
	Vacuum	KPa	-90	-92	-88
	Vacuum time	Mins	N/A	10	45
Heating	Temperature at the end of heating	°C	53	50	60

Heating keeping	Heat keeping Time	Mins	10	9	12
Steam Injection	Delta P of steam injection	KPa	2	1	3
Humidity conditioning	Humidity conditioning time	Mins	20	18	22
	Humidity at the end of humidity conditioning	%RH	N/A	30	85
Sterilizing Agent Injection	Delta P During EO Injection	KPa	43	42	44
	Injection inlet temperature during EO injection stage	°C	N/A	15	60
	EO injection time	Mins	N/A	45	90
	Injected EO weight for 100M ³ size ETO sterilizer	Kg	N/A	65	132
Exposure	Exposure Temperature	°C	53	50	60
	Exposure Humidity	%RH	N/A	30	85
	Exposure Dwell time	Mins	272	270	274
Nitrogen Rinsing	Nitrogen rinsing times	N/A	1	1	1
	Nitrogen rinsing vacuum #1	KPa	-90	-92	-88
	Nitrogen rinsing vacuum time #1	Mins	N/A	7	45
	Pressure after nitrogen rinsing#1	KPa	-10	-12	-8
	Nitrogen rinsing time #1	Mins	N/A	7	30
Air Rinsing	Air rinsing times	N/A	3	3	3
	Air rinsing vacuum #1	KPa	-90	-92	-88
	Pressure after air rinsing#1	KPa	-10	-12	-8
	Air rinsing vacuum #2	KPa	-90	-92	-88
	Pressure after air rinsing#2	KPa	-10	-12	-8
	Air rinsing vacuum #3	KPa	-90	-92	-88
	Pressure after air rinsing#3	KPa	-10	-12	-8
	Air Rinsing1# 2#3# time	Mins	N/A	7	30
Exit	Exit Pressure	KPa	-3	-5	N/A
Circulation Fan	Status of the whole EO sterilization process	N/A	Runing	0	

Aeration Process

Steps	Process	Parameter items	Unit	Set point	Acceptable Range	
					Min value	Max value
Step 1	Additional air rinsing within sterilizer	Air rinsing vacuum	KPa	-90	-92	-88
		Pressure after air rinsing	KPa	-10	-12	-8
		Exit Pressure	KPa	-3	-5	N/A
		Air rinsing times	Times	2	2	N/A

Step2	Aeration in natural degassing room	Aeration dwell time	Hours	54	54	N/A
			Hours	48	48	N/A
			Hours	96	96	N/A
			Hours	0	0	N/A
			Hours	72	72	N/A
			Hours	168	168	N/A

4. Post-Sterilization Handling

Remove products from the sterilization chamber and cool down at room temperature for at least 24 hours. Inspect sterilization pouches for any damage.

5. Storage before Sterilization

Prior to use, it is recommended that the maximum storage time before sterilization is 5 years, store the product in a clean, dry, and ventilated area, avoid direct sunlight, high humidity

6. Transportation Requirements

Transport with clean containers; take care to avoid package damage.

【Warnings and Precautions】

- Stop using if product has any defect.
- The product is disposable and cannot be reused, reuse may lead to patient infection.
- Stop using if the product has expired.
- The product is not intended used for surgery of central nervous system nor central circulation system.
- Do not fully unfold the product during use.
- Sterilization using the recommended parameters is permitted for a maximum of two cycles. Additional cycles are not validated and may affect product performance.

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【Shelf Life】 5years

【Contraindications】

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

【Side Effects】

There are currently no known adverse reactions directly associated with the use of this product.

【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.

【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

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	Do not use if package is damaged		Keep away from sunlight		Keep dry		Importer
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