

Instruction for Use

【Product Name】

Non-Sterile OR Towel (with x-ray thread)

【Product Composition】

The product is mainly composed of bleached white or dyed gauze and x-ray thread.

【Intended Use】

It's a kind of invasive dressing, which penetrates inside the body used for absorption of exudates or protecting organs/tissues in surgical operation. 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】

- Medical staff should clean and disinfect hands to ensure aseptic operation.
- Non-sterile product should be sterilized before use, check packaging and product are intact before use.
- Open the package take out the product and make it cover the surgical area according to the size and shape of the surgical field.

【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

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
	Initial product temperature when starting preconditioning process	°C	N/A	2.5	N/A
	Preconditioning time	Hrs	N/A	22	48
	product temperature at the end of preconditioning process	°C	N/A	37	N/A
Product transfer	Transfer time	Mins	N/A	0	60
Sterilization Process	Process Parameter	Unit	Set point	Acceptance range	
				Min value	Max value
Initial Vacuum	Initial vacuum	KPa	-90	-92	-88
	Initial vacuum speed	Kpa/min	4	1	4.5
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 speed	Kpa/min	6	4.5	6.5

	Vacuum	KPa	-90	-92	-88
	1# Nitrogen Vacuum Speed	Kpa/min	4	1	4.5
Heating	Temperature at the end of heating	℃	52	49	58
Heating keeping	Heat keeping Time	Mins	10	9	12
Steam Injection	Delta P of steam injection	KPa	2	1	3
	Steam injection time	Mins	N/A	0	50
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	40	39	41
	Injection inlet temperature during EO injection stage	℃	N/A	15	60
	EO injection rate	kPa/min	0.7	0.4	1
	Injected EO weight	Kg	N/A	32	100
Exposure	Exposure Temperature	℃	52	49	58
	Exposure Humidity	%RH	N/A	30	85
	Exposure Dwell time	Mins	272	270	274
Nitrogen Rinsing	Nitrogen rinsing times	N/A	2	2	2
	Nitrogen rinsing vacuum #1	KPa	-90	-92	-88
	Pressure after nitrogen rinsing#1	KPa	-10	-12	-8
	Nitrogen rinsing vacuum #2	KPa	-90	-92	-88
	Pressure after nitrogen rinsing#2	KPa	-10	-12	-8
	Nitrogen rinsing 1#2# Vacuum Speed	Kpa/min	4	1	4.5
	Nitrogen rinsing 1#2# injection speed	Kpa/min	6	4.5	6.5
Air Rinsing	Air rinsing times	N/A	2	2	2
	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 Rinsing1# 2#Vacuum Speed	Kpa/min	4	1	4.5
	Air rinsing #1 speed	Kpa/min	5.5	4.5	5.8
Exit	Exit Pressure	KPa	-3	-5	N/A
Circulation Fan	Status of the whole EO sterilization process	N/A	Runing	0	

Heated aeration process	Parameters items	Unit	Target Value	Acceptable Actual Value	
				Min value	Max value
Heated aeration parameters	Temperature	°C	40	30	50
	Aeration time	Hrs	24	24	96
Other settings	Exhaust valve opening: 80%, exhaust valve open frequency: open 5mins and then close 15mins alternatively.				

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.

- Sterilization using the recommended parameters is permitted for a maximum of two cycles. Additional cycles are not validated and may affect product performance.

【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.

Document Name: Instruction for Use

Document No.: IFU-ORTXR-NS-M02010502-02

Product : Non-Sterile OR Towel(with x-ray thread)

Version: 02



【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

【Manufacturer】 Allmed Medical Products Co., Ltd

【Address】 No.18 Qixing Road, Majiadian Town, 443200 Zhijiang City, Hubei Province , CHINA

【European Representative】 Shanghai International Holding Corp. GmbH(Europe)

【Address】 Eiffestrasse 80, 20537 Hamburg, Germany

【Revision Date】 2025-12-01

