

	Chest seal	Doc no.:NCXF-PZXF0037-05
	Instruction for use	Ver. A/1

Instructions For Use

Product Name

Chest seal

Product Composition

Chest Seal is a self-adhesive occlusive dressing designed for the treatment and management of an open chest wound caused by a penetrating trauma, such as a gunshot or stab wound. A penetrating chest wound creates an opening in the chest wall through which air can enter the chest cavity; commonly referred to as an "open pneumothorax." Chest Seal utilizes an enhanced adhesive gel formulation designed to create a superior seal even in extreme conditions to treat and manage an open pneumothorax while preventing the development of a “tension pneumothorax,” which is one of the top three leading causes of preventable deaths on the battlefield. It's composed of a backing film, hydrocolloid, a protective film, and gauze. The product has been sterilized by E-beam radiation and is disposable.

Model&Specification

Models	Types	length(mm)	width(mm)	gauze(mm)
		±5mm		±10mm
PZXF0037	4 vents	167	203	100×100,2 pieces
PZXF0038	3 vents	167	217	100×100,2 pieces
PZXF0039	non-vent	167	217	100×100,2 pieces
PZXF0040	4 vents	160	195	100×100,2 pieces
PZXF0041	non-vent	160	195	100×100,2 pieces
PZXF0079	Twin Pack	Combination packs PZXF0038 and PZXF0039		100×100,4 pieces
PZXF0081	4 Vented Channels	167	217	100×100,2pieces
PZXF0082	3 Vented Channels	160	230	100×100,2pieces
PZXF0083	4 vents	167	217	100×100,2 pieces

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[Division description]

Divide the product into 9 specifications based on shape and vents.

Intended Use

Intended used for nursing of superficial wound after chest puncture operation.

[Intended user]

The user shall be trained medical staff or first-aid personnel of medical institutions

[patient population]

Adults and children

Warning

Please read the instructions and precautions carefully before using this product!

1. Check whether the packaging is in good condition before use, and confirm the outer packaging mark, production date, and validity period, and use it within the validity period.
- 2.The device should not be used in toxic or hazardous atmospheres.
- 3.Dispose the product after use to comply with local regulation.
- 4.Chest seal is sterilized product. If the package is damaged, it cannot be used.
- 5.Please wear gloves before use. Do not touch the product directly with your hands.
- 6.Chest seal is disposable product, please do not reuse it.

Contraindications

Hydrocolloid allergy

Instructions for Use

1. Expose and uncover any chest wounds.

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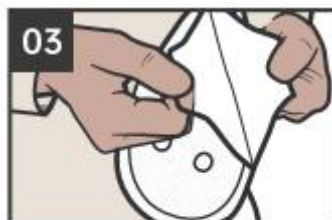
01
EXPOSE and uncover any chest wounds.

2. Open the outer wrapper of the chest seal.



02
OPEN the outer wrapper of the chest seal vented.

3. Peel off the protective liner, exposing the adhesive portion of the seal.



03
PEEL OFF the protective liner, exposing the adhesive portion of the seal.

4. Place pressing on patient's wound, adhesive side down.



04
PLACE pressing on patient's wound, adhesive side down.

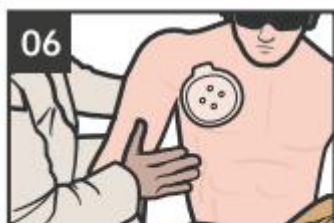
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5. Press dressing firmly to skin to assure an occlusive seal.



Press dressing firmly to skin to assure an occlusive seal.

6. Place conscious casualty into a sitting position or an unconscious casualty in the recovery position(with their injured side down)..



PLACE conscious casualty into a sitting position or an unconscious casualty in the recovery position (with their injured side down).

Store and transportation

1. Products should be stored in 0-35℃, relative humidity 20%-80%, no corrosive gas and well-ventilated, clean indoor, and prevent from extrusion, wear and impact. Away from high temperature and humidity, and protected from direct sunlight.
- 2.It is strictly forbidden to mix with toxic and harmful substances. Transport should also avoid moisture and heat during transportation, do not connect with sharp objects or heavy weigh.

[Period of validity] 5 years

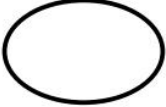
[Expiry date] See package

Disposal

Please dispose the product after use to comply with local regulation.

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Explanation for the Symbols on the Label

	Do not reuse		Unique device identifier
	Model number		Country of manufacture
	Don't use when packing damaged		Do not re-sterilize
	Manufacturer		Lot number
	Attention, see instruction for use		Date of manufacture
	Consult instructions for use		Use until year & month (Expiration date)
	Method of sterilization		Authorized representative in the EC
	Importer		Distributor
	Sterile barrier system		Medical Device
	Keep away from sunlight		Keep dry
	Humidity limitation		Temperature limitation
	CE-mark and identification number of Notified Body. Certified according with MDR		

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Manufacturer



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European Authorized Representative



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[Release of instructions]

1. Instruction No: NCXF-PZXF0037-05
2. Effective date: January 13, 2025

Version History

Version No.	Preparation date	Description
A/0	November 29, 2022	Initial release.
A/1	January 13, 2025	Add specification models.