Emergency Relief Patient Cover™

Operations Manual

REF 6019



Symbols

[]i	Consult instructions for use
<u>^</u>	General warning
<u> </u>	Caution
REF	Catalogue number
	Manufacturer
2	Single use device
US Patents	For US Patents see www.stryker.com/ patents
MADE IN U.S.A.	Product made in the United States of America

Summary of safety precautions

WARNING

The personal safety of the patient or user may be involved. Disregarding this information could result in injury to the patient or user.

CAUTION

These instructions point out special procedures or precautions that must be followed to avoid damaging the equipment.



WARNING

- Always monitor the patient when the product is in use.
- Always make sure that there is proper air flow inside the product.
- Do not touch the interior surface of the patient cover when you remove it from the patient surface.
- Always follow current protocols governing the safe removal, handling, and disposal of potential biohazard waste.
- Do not expose the product to open flames.
- Do not use the product if it impedes your ability to perform a medical procedure on a patient.

Note

- Always wear any appropriate personal protective equipment to avoid exposure to potentially infectious pathogens. The product is not intended to replace personal protective equipment.
- Before you use the product, assess the patient for respiratory status and difficult airway.

For United States only:

- The product has not been FDA cleared or approved.
- The product has been authorized by the FDA under an Emergency Use Authorization for use by healthcare providers when caring for or performing medical procedures on patients who are known or suspected to have COVID-19. The product is intended for use in healthcare settings to prevent healthcare provider exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection, in addition to personal protective equipment.
- This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under section 564(b)(1) of the Act 21 U.S.C. section 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

Product description

The Emergency Relief Patient Cover is a transparent protective barrier enclosure that covers the head and shoulders of a patient in a supine position while on a support surface. There is a draped covering at both ends of the device to allow healthcare providers access to a patient. There is a lower strap to secure the product to an ambulance cot.

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Indications for use

The Emergency Relief Patient Cover covers the head and shoulders of a patient to act as an additional layer of protection, in addition to personal protective equipment, against airborne particles or droplets from patients.

The product is intended for use with human patients only during the duration of the COVID-19 pandemic.

The benefits/risks of using the product for airway management in certain patient populations should be predetermined by a healthcare provider. These populations include but are not limited to:

- Patients who require emergency endotracheal intubation who have severe respiratory compromise
- Patients with anticipated or known history of difficult airways
- Patients who are morbidly obese
- · Pregnant women in the second or third trimester
- Patients with severe claustrophobia or confined space anxiety
- · Patients with certain communication disorders
- · Patients with anatomical abnormalities
- Patients with decreased neck mobility due to arthritis or other causes

Intended users of this product include healthcare professionals such as physicians, nurses, and emergency first responders. The product is intended to be used in healthcare settings, such as pre-hospital, hospital, emergency medical vehicles, or where healthcare providers must care or perform medical procedures on patients.

Expected service life

The Emergency Relief Patient Cover is a disposable, single use device.

Environmental conditions	Storage and transportation
Temperature	-4 °F (40 °C) (-20 °C)
Relative humidity	93%
Atmospheric pressure	1060 hPa

Cot compatibility

You can secure the **Emergency Relief Patient Cover** to the following cots to limit movement during transport:

Power-PRO™ XT

M-1ℝ

Performance-PRO™ XT

• MX-PRO® R3

Positioning the patient cover

You can position the patient cover before or after a patient is on the patient surface. Twist the flexible rods to help the patient cover pop open.

- 1. Align the patient cover over the head end of the patient surface.
- 2. Position the upper strap on top of the mattress (Figure 1).



Figure 1 – Position the upper strap

Note

- If a patient is already on the patient surface, gently lift the patient's head to position the upper strap.
- On a cot, make sure that the upper strap does not interfere with the shoulder restraint straps.
- 3. To secure the patient cover to a patient surface with the lower strap:
 - a. Wrap the lower strap around the backrest frame.

Note

- On a cot, you can route the lower strap under the equipment hook (Figure 2) or between the backrest and the backrest adjustment handle.
- Make sure that the lower strap does not activate the backrest adjustment handle.

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Figure 2 – Route the lower strap

b. If you cannot use the lower strap, tuck the lower strap where it will not interfere with the operation of the patient surface or create a trip hazard. The optimal patient position is flat on the patient surface.

Note

- If the patient's condition requires an adjustment to the backrest, evaluate the patient cover to make sure that it provides appropriate coverage.
- Only the patient's body weight will hold the patient cover on the patient surface without use of the lower strap.
- c. Pull the upper strap tight and secure with **Velcro**® (Figure 3).



Figure 3 – Secure with Velcro

Drape the semi-transparent sheet over the patient's waist.

Note - If the patient cover is already secured with the lower strap and **Velcro**, pull the collapsible rod toward the head end so you can load the patient onto the patient surface.

Removing the patient cover

 Pull toward the head end to remove the patient cover from the patient surface. Do not touch the interior surface or shake the patient cover to avoid spreading potentially infectious pathogens.

Note - If removing from a cot, detach the **Velcro** before you pull the patient cover.

2. Collapse the patient cover for disposal.



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6019-009-001 Rev A.4 WCR: AA.19