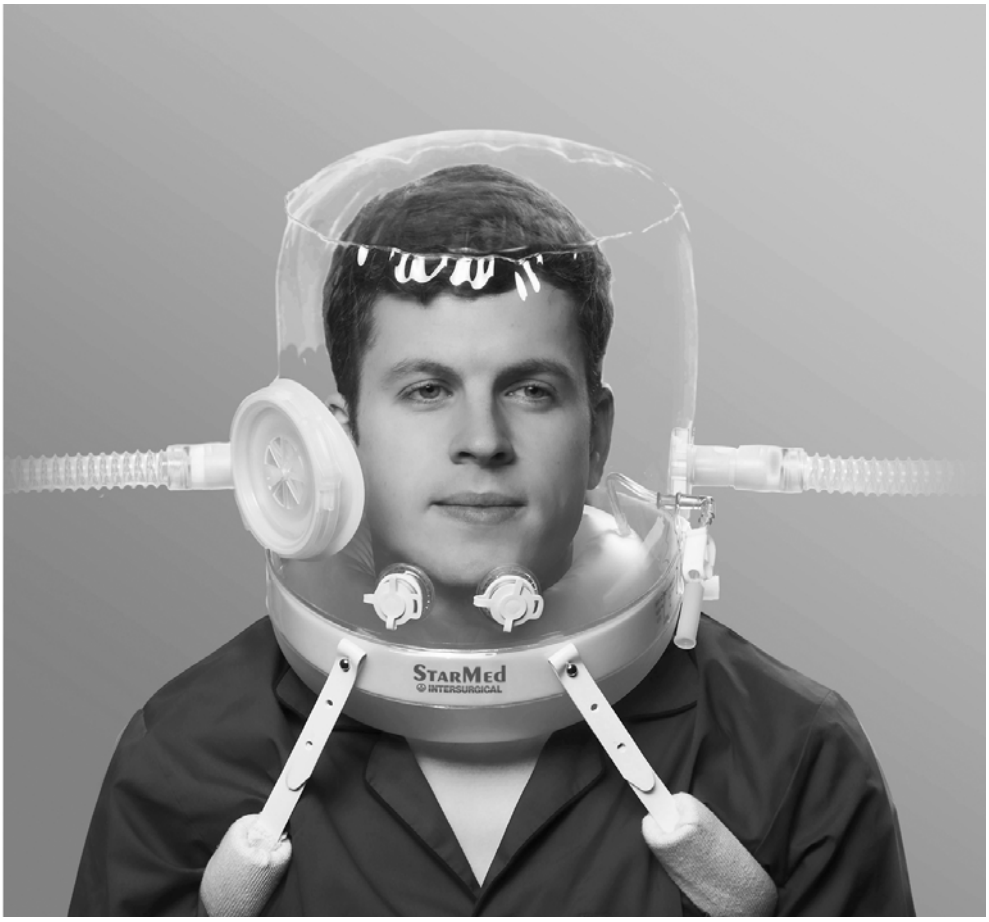
StarMed CaStar R Hood

For Non-Invasive Ventilation (N.I.V.) and CPAP



Instructions For Use

INTERSURGICAL®
COMPLETE RESPIRATORY SYSTEMS

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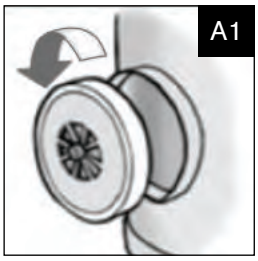
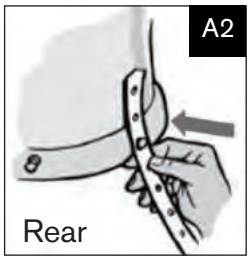
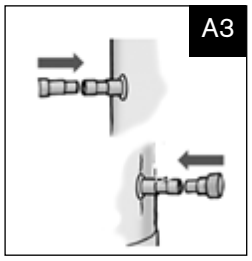
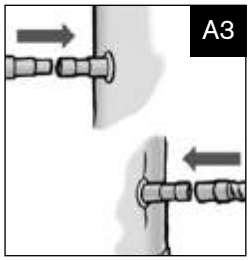
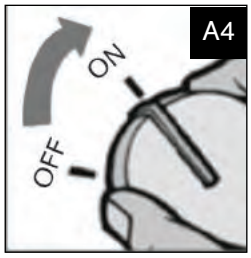
COMPLETE RESPIRATORY SYSTEMS

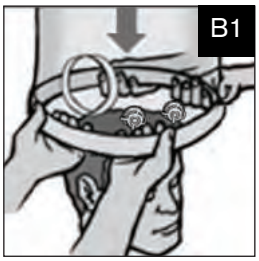


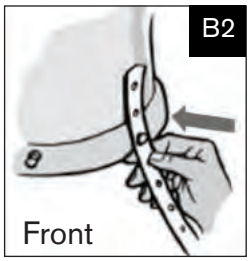


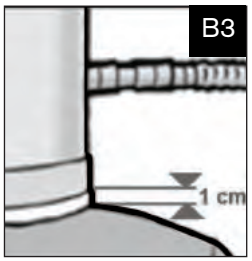


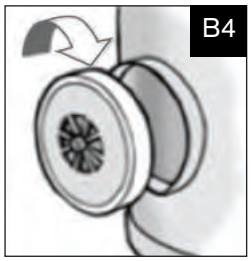


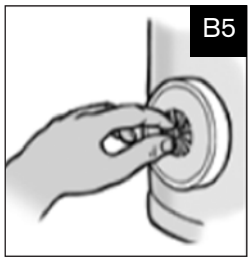


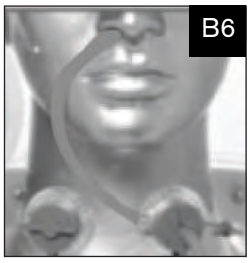


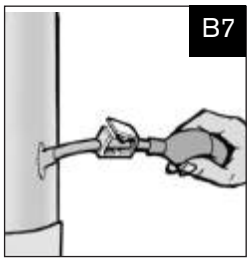


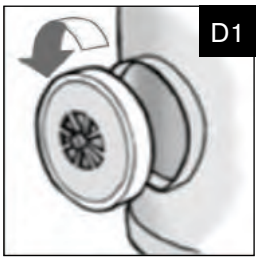


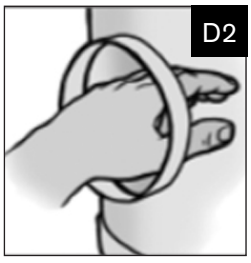


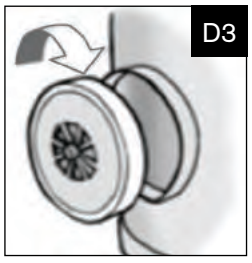


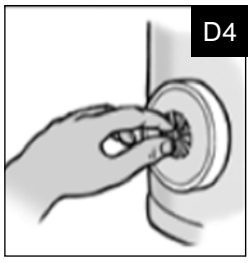


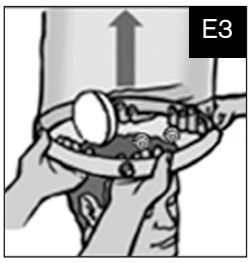


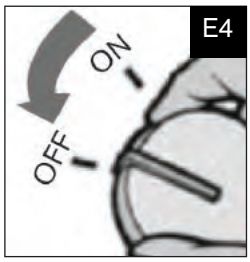




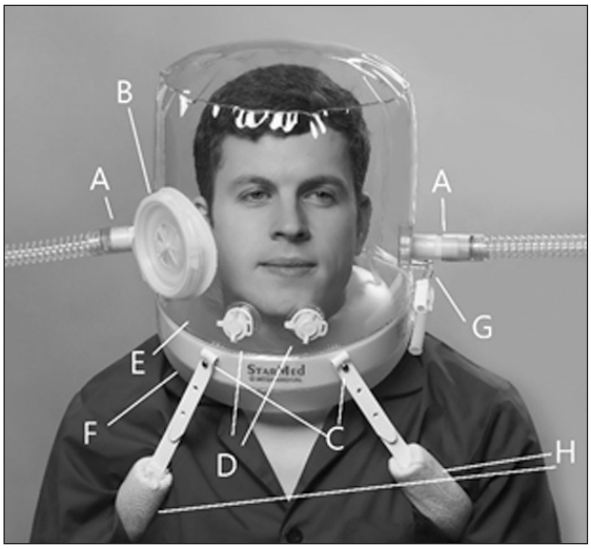








INTERSURGICAL® COMPLETE RESPIRATORY SYSTEMS



A	Inlet/outlet connector (22mm Male per ISO 5356-1)
B	Bi-directional anti-asphyxiation valve / Patient access port
C	Hooks for underarm fastening straps
D	Sealed access ports for probes or catheters
E	Inflatable neck cushion
F	Collar
G	Neck cushion inflation line
H	Underarm fastening straps

Technical specifications

Internal volume (neck cushion deflated)	Approximately 12 liters
Internal volume (neck cushion inflated)	Approximately 11 liters
Therapy Pressure	Allowed maximum pressure 30 cmH_2O
Bi-directional anti-asphyxiation valve open to atmosphere pressure	2 cmH_2O
Bi-directional anti-asphyxiation valve closed to atmosphere pressure	The bi-directional anti-asphyxiation valve is normally closed when the internal pressure is above 2 cmH_2O
Inspiratory and expiratory resistance with bi-directional anti-asphyxiation valve open to atmosphere	Inspiratory 0.19 hPa per l/s (0.16hPa) Expiratory 0.24 hPa per l/s (0.20hPa)
Pressure drop with bi-directional anti-asphyxiation valve closed to atmosphere	0.06 cmH_2O @ 50 l/min 0.27 cmH_2O @ 100 l/min
Connection dimensional characteristics	Male connectors 22 mm per ISO 5356-1

Indications for use
Helmet for non-invasive ventilation and CPAP in the hospital environment. The treatment may only be performed under careful monitoring by expert operators.
Suitable for treatment of respiratory insufficiency in hypoxemic / hypercapnic adult patients.

Product use
The use of an overpressure valve is recommended on the interface or within the breathing system, please contact your local Intersurgical representative for more details.

Contraindications
- Coma
- Uncooperative patient
- Cardiac arrest
- Hemodynamic instability
- Recent esophageal and gastro-surgical operations
- Heavy bleeding of the upper digestive tract
- Obstruction of the upper airways
- Pneumothorax
- Treatment in the home environment

INTERSURGICAL® COMPLETE RESPIRATORY SYSTEMS

Restrictions of use

- The device must be used by qualified and trained medical/nursing staff. When used with a ventilator, the patient/ventilator interaction (trigger) may be complex, therefore the device should only be used by expert operators.
- To be used for administration of air and oxygen.
- For providing CPAP therapy, use flow generators that are capable of providing a continuous air and oxygen flow of at least 40 L/min in order to ensure good washout of the exhaled CO_2. When used with a ventilator, make sure that during the inspiratory phase the equipment is capable of delivering sufficient flow to quickly remove the CO_2 from the inside of the helmet.
- If used correctly, the device may be used continuously for a maximum of 7 days, after which it must be replaced.
- Monitor the clinical parameters of the patient.
- The device is intended to be used in a hospital environment and it cannot be used for homecare treatments.
- Do not use near MRI devices because the presence of metallic parts in the helmets could interfere with MRI diagnostical devices.

Size Selection

The medical/nursing staff is responsible for choosing the most suitable device for the patient in terms of configuration and size. The selection of the appropriate size will ensure a good seal around the patient's neck and torso.
It is recommended to use the included measuring tape to choose the best size according to the patient's neck circumference.

Patients	Recommended Size
ADULT - weight > 30 kg	ADULT XS-S-M-L-XL-XXL, based on the neck circumference indicated on the label

Complications/side effects

- Pain and/or skin redness (axillae, neck, nape) in patients with fragile skin and in prolonged therapies
- Claustrophobia
- CO_2 retention (rebreathing)

SETTING UP THE DEVICE (see pictures page 1)

Remove the device from the package and model it to restore its cylindrical shape.

A1. Open the access port before positioning the helmet on the patient. Pre-check the functioning of the anti-asphyxiation valve. Pull and release the button checking that the components slide smoothly.

A2. Secure the fastening straps on the rear of the helmet.

A3. When used with a flow generator in CPAP

Connect the breathing system to the inlet connector. Connect a PEEP valve to the outlet connector. It is recommended to set a minimal PEEP of 5 cmH_2O as prescribed by the physician. An external manometer can be connected to one of the sealed access ports for monitoring actual therapy pressure.

When used with a ventilator

Connect the breathing systems to the inlet and the outlet connectors.

A4. Check that the connection is secure before proceeding with administration of the therapy. Activate the ventilation flow before continuing with the next positioning phase in order to minimize the time required to pressurize the helmet.

POSITIONING AND ACTIVATING THE DEVICE

B1. Firmly open the collar so that the patient's head can pass through. To facilitate fitting the helmet, it is suggested that the collar is opened by two people using their finger tips and thumbs along the rigid ring of the helmet.

B2. Complete positioning of the fastening straps under the patient's arms and attach to the front of the helmet.

B3. Adjust the length of the straps so that the rigid ring rests approximately 1 centimeter above the patient's shoulders.

B4. Close the patient access port.

B5. Pressurize the system by pulling the button of the anti-asphyxiation valve until the helmet reaches the desired internal pressure. The anti-asphyxiation valve activates when the pressure within the helmet drops below 2 cmH_2O. For proper functioning of the valve, do not obstruct the valve opening area and do not lock the opening mechanism.

B6. The helmet features sealed access ports for probes or catheters with diameters between 3.5 and 7 mm.

B7. The neck cushion can be inflated through its inflation line. Close the clamp to avoid the deflation of the cushion.

OPERATIONS TO IMPROVE PATIENT'S COMFORT

C1. Alternative fastening systems

As a result of extended application with high therapy pressure some nursing care is advised to alleviate axillae pain and redness. Some hydrocolloid tape may be applied between the patient's skin and the underarm fastening straps. If appropriate elastic straps can eventually be used to fix the helmet to the bed.

USING THE PATIENT ACCESS PORT

D1. Open the patient access port by turning the anti-asphyxiation valve counter clockwise.

D2. Perform nursing operation.

D3. Close the patient access port by turning the anti-asphyxiation valve clockwise.

D4. Pull the button of the anti-asphyxiation valve using two fingers until the helmet is pressurized.

HOW TO REMOVE THE HELMET

E1. Deflate the neck cushion by opening the clamp on its inflation line. Open the patient access port and remove any probes/catheters used during the therapy from the sealed access ports.

E2. Undo the fastening systems.

E3. Two people firmly open up the collar and remove the helmet.

E4. Switch off the ventilation flow.

WARNINGS / PRECAUTIONS

- **Single use device.** Reuse is not allowed since it could cause cross contamination in patients. Moreover, the materials of the device could be damaged by disinfection methods, the product performances may be impaired developing a safety risk for patients.
- To avoid cross contamination/spread of infection, use of compatible bacterial/viral filters are recommended on inspiratory and expiratory limbs. Filters should be replaced as needed and should not impede flow.
- In the event of an evident change in performance or inadequate performance of the device, it is recommended to replace it.
- Continuous monitoring of helmet pressure, vital signs (e.g. SpO_2, RR) is recommended.
- If the patient's conditions deteriorate or there is no improvement within the expected time, it is recommended to evaluate alternative ventilation techniques.
- The efficacy of the therapy is considerably affected by the set PEEP values. Therefore, the medical staff are advised to carefully evaluate the pressure level suiting the clinical condition of the patient. Using too low pressure may not be sufficient for alveolar recruitment. Using too high pressure may be a source of alveolar overdistension.
- **Caution:** The device contains metal; do not use in areas where the presence of metal is a source of risk for the patient or others.
- The flow through the interface may generate some noise, thus limiting patient comfort. This can be reduced by placing respiratory filters on the inlet/outlet of the helmet (silencer) when active humidification is not in place. Ear plugs can be worn by the patient if appropriate.
- When used with active humidification, check that increased internal temperature and condensation do not cause patient discomfort.
- The patient must remove all small objects such as earrings, hair clips, combs and any other personal accessories.
- The physician is responsible for outlining the most appropriate ventilation therapy for the patient. The medical/nursing staff is responsible for choosing the most suitable device for the patient in terms of configuration and size. The neck circumferences range (expressed in centimeters) and the helmet size is indicated on each device labelling. The selection of the appropriate size will ensure a good seal around the patient's neck and torso.
- Use only on unbroken skin.
- The device can be used for maximum 7 days. Depending on the clinical condition of the patient, the medical/nursing staffs are responsible for defining the need for more frequent replacement of the device.
- Non-sterile. Do not sterilize.
- Do not use on another patient.
- Expiry: 5 years provided that the packaging is undamaged and the product is stored in normal storage conditions (-20°C/+50°C).
- To facilitate modeling/shaping of the helmet, it is recommended to keep it at room temp. (approximately 20-25°C) for a few hours before use.
- Dispose of the materials immediately after use in compliance with the current laws and regulations.
- The pump for inflating the neck cushion is not provided with the helmet, but it is available as accessory. Do not use pressurized gas sources to inflate the neck cushion.
- Once activated in case of treatment failure, the bi-directional anti-asphyxiation valve allows gas exchange between the inner helmet volume and the external environment, thus reducing the CO_2 build up inside the interface. The anti-asphyxiation valve does not substitute the ventilation support in the event of accidental ventilation interruption. **The anti-asphyxiation valve does not exempt the nursing staff from implementing appropriate monitoring and supervision of the patient.**
- **Caution**: The use of the helmet on a patient does not exempt operators from the use of adequate Personal Protection Equipment in accordance with the hospital procedures.
- Non-invasive ventilation shall be discontinued if one of the following conditions occurs:
    - Worsening of the consciousness status or worsening of the respiratory distress
    - Loss of airway protection
    - Unchanged $PaCO_2$ (during two subsequent EGA performed after max 1 hour)
    - Persistence of severe hypoxemia
    - Severe and uncontrollable hemodynamic instability
    - Patient / ventilator synchronization issues
    - Uncontrollable secretions
    - Intolerance to the interface

- **Oxygen Toxicity**: the toxic effects of oxygen may have damaging effects on the eye, particularly the lens. The most commonly reported symptoms are eyelid twitching, blurry vision, myopia, cataracts and visual-field disturbances.
- If oxygen is used with the device, the oxygen flow must be turned off when the ventilator is not operating, so that unused oxygen does not accumulate within the device enclosure and create a risk of fire.
- Do not block or try to seal the bi-directional anti-asphyxiation valve.
- The device is not for use on patients with impaired laryngeal reflexes or other conditions predisposing to aspiration in the event of regurgitation or vomiting.
- The device should not be worn unless the ventilator system is turned on and operating properly.
- Air swallowing due to sustained elevated pressure (aerophagia) may lead to aspiration.
- Lungs can be damaged by elevated pressure. Any accidental blockage of the outlet can lead to excess pressure.
- Ensure fittings supplying gas flow are secure and do not disconnect thereby interrupting gas supply.
- Electronic devices, such as microphones, headphones, cell phones and electromedical devices, used inside or in the vicinity of the VAH shall be suitable for use in an oxygen enriched environment > 25% O_2.
- To avoid the risk of fire and burns do not use lotions, salves, dressing or makeup unless they are Oxygen compatible.
- Do not use lubricant for any fittings, connections, tubing, or other accessories unless certified for use in an oxygen enriched atmosphere to avoid the risk of fire and burns.

The Intersurgical StarMed CaStar R NIV Hood is authorized by the FDA for the emergency use of ventilators, ventilator tubing connectors, and ventilator accessories under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1).

INTERSURGICAL®
COMPLETE RESPIRATORY SYSTEMS

SYMBOL LEGEND	
MOD	Model/Size
REF	Code
LOT	Batch
	Expiry date
QTY	Quantity
	Do not re-use
	Caution
	See instructions for use attached to the device
	Manufacturer
	Do not use if the package is damaged
	Non-sterile
	Temperature limitations
	Neck circumference
	Do not open packaging using a knife
CE 1936	The CE marking includes the TUV Rheinland Italia (notified body) identification number. The product conforms to the essential requirements set out in the European Medical Device Directive 93/42/EEC
	Handle with care
	Keep away from sunlight
	Keep away from rain
	Phtalates free
	Latex free
	Not MRI Safe
Rx ONLY	The device can be used only after a physician prescription

StarMed
INTERSURGICAL

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CE 1936

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