

Prometheus Steady Head™

Disposable Head Blocks

Contents

- Two 20cm x 8cm x 15cm head blocks
- One matching sized base plate
- One roll of 2.5cm x 5m adhesive tape

Intended Use

The Steady-Head™ is intended to be used to aid support and stabilisation of a patient's head and neck on devices such as orthopaedic 'scoop' stretchers or extrication boards.

User Profile

To be used by medical professionals trained in spinal immobilization in the pre-hospital setting to immobilize suspected spinal injuries.

Product Claims

- Compatible with standard extrication boards and scoop stretchers
- Single-Use Device (disposable)
- Lightweight
- Robust (Function is not impaired by wet, muddy or sandy conditions or extreme temperatures)
- X-Ray Translucent
- Quick to deploy
- Non-Absorbent

Patient Profile

Indicated for use on all patients with suspected unstable spinal injury in the pre-hospital emergency setting.

Clinical Benefits

To stabilise the patient's head for up to 24 hours, until definitive care is reached.

Contraindications

N/A

Performance Characteristics

- Constructed from comfortable foam
- Ear holes to monitor patients' ear canal and facilitate communication

Residual Risks/Warnings

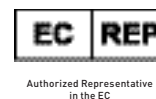
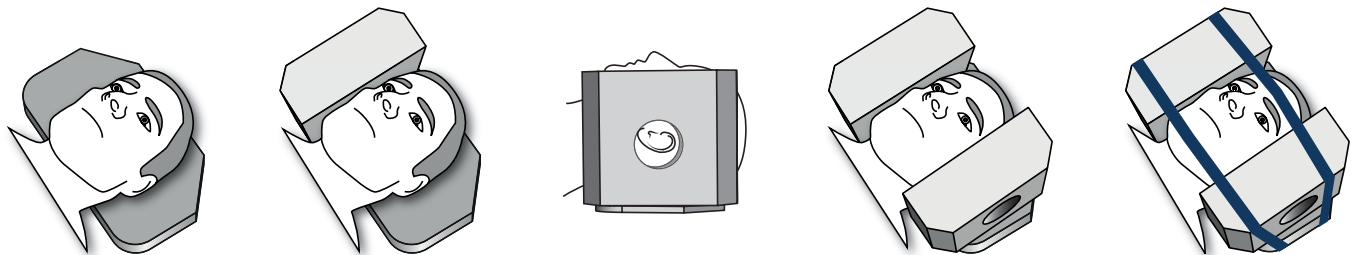
- The device is intended for single use only. Reuse will risk cross infection and loss of product functionality
- Use beyond expiry date will risk loss of product functionality
- After use, the device should be disposed of as clinical waste as per local protocols. Failure to dispose of as clinical waste will risk cross-contamination
- Device must be stored out of direct sunlight, Prolonged exposure to sunlight will risk degradation of packaging
- Do not expose device to a naked flame
- For use up to 24 hours. Prolonged stabilisation on a long board with headblocks might lead to pressure at the occiput leading to pain and skin damage

Instructions for Use

1. Tear open packaging at perforation site.
2. Remove head blocks, base plate and tape.
3. Place base plate on the orthopaedic stretcher/extrication board and position patient's head appropriately. Move blocks against the head and the block openings to the patient's ears.
4. Pull the tape over the head blocks while centring on the patient's forehead and secure to the back of the orthopaedic stretcher/ extrication board on the other side. Repeat for the patient's chin area.

Reporting

Any serious incident that has occurred in relation to this device should be reported to manufacturer vigilance@safeguardmedical.com and applicable national competent authority.



Safeguard Technologies Ltd
Willow Grove, Delgany, A63 XY89
Co Wicklow, Ireland



Safeguard Medical Technologies Ltd.
The Old Rectory
Hope Under Dinmore
Herefordshire, HR6 0PW
United Kingdom